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No. _____

In The Supreme Court of the United States

LIFESTAR AMBULANCE SERVICE, INC., *et al.*,

Petitioners,

v.

UNITED STATES OF AMERICA, *et al.*,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. Whether the Eleventh Circuit's decision forecloses mandamus jurisdiction for all claims arising under the Medicare Act by effectively ruling that no claim arising under the Medicare Act will ever meet the test for mandamus jurisdiction, thus conflicting with the nine other circuits that had addressed this issue and uniformly agreed that the jurisdiction-limiting provision of the Medicare Act, 42 U.S.C. § 405(h), does not bar consideration of whether mandamus jurisdiction lies pursuant to 28 U.S.C. § 1361.

2. Whether the jurisdictional provision in the Medicare Act, 42 U.S.C. § 405(h), forecloses the exercise of mandamus jurisdiction pursuant to 28 U.S.C. § 1361 for claims arising under the Medicare Act.

LIST OF ALL PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

Petitioners Lifestar Ambulance Service, Inc., individually and on behalf of a class of all entities similarly situated; Coastal Medical Transport, Inc., individually and on behalf of a class of all entities similarly situated; and Ambulance Services, Inc., individually and on behalf of a class of all entities similarly situated were plaintiffs and appellees in the proceedings below.

Respondents United States of America; the Department of Health and Human Services; Tommy Thompson in his official capacity as Secretary/Director of the D.H.H.S.; the Health Care Financing Administration (Centers for Medicare & Medicaid Services); and Thomas A. Scully, in his official capacity as Secretary/Director of the H.C.F.A./ C.M.S. were defendants and appellants in the proceedings below.

Pursuant to Supreme Court Rule 29.6, Petitioners state as follows: Lifestar Ambulance Services, Inc. is a Georgia corporation, and there is no parent or publicly held company owning 10% or more of such corporation's stock. Coastal Medical Transport, Inc. is a North Carolina corporation, and there is no parent or publicly held company owning 10% or more of such corporation's stock. Ambulance Services, Inc. is a Tennessee corporation, and there is no parent or publicly held company owning 10% or more of such corporation's stock.

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CITATIONS OF REPORTS OF OPINIONS ENTERED IN THE CASE

The opinion of the United States Court of Appeals for the Eleventh Circuit (App. 1a) is reported at *Lifestar Ambulance Service, Inc. v. United States*, 365 F.3d 1293 (11th Cir. April 16, 2004). The opinion of the United States District Court for the Middle District of Georgia (App. 12a) is reported at *Lifestar Ambulance Service, Inc. v. United States*, 211 F.R.D. 688 (M.D. Ga. Jan. 16, 2003).

BASIS FOR SUPREME COURT JURISDICTION

The United States Court of Appeals for the Eleventh Circuit entered its judgment on appeal from the District Court for the Middle District of Georgia on April 16, 2004. App. 1a. The United States Court of Appeals for the Eleventh Circuit denied a petition for rehearing en banc on June 29, 2004. App. 44a. The present petition is timely filed under 28 U.S.C. § 2101(c) and Rule 13.3 of this Court, and this Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED IN THE CASE

"The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. App. 46a.

"The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter." 42 U.S.C. § 405(h). App. 46a (including subsections (a), (g), & (h) of 42 U.S.C. § 405).

"The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (*l*) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively." 42 U.S.C. § 1395ii. App. 48a.

In addition to the above statutory provisions, the following statutes and regulations are involved in this case and their pertinent text is set forth in the appendix:

42 U.S.C. § 1395m(l). App. 49a.

Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4531(b)(2) & (3), 111 Stat. 251 (1997) (codified in part at 42 U.S.C. § 1395m(l)). App. 53a.

Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554,

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Medicare Program; Notice of Ambulance Fee Schedule in Accordance With Federal District Court Order, 68 Fed. Reg. 18654 (April 16, 2003). App. 227a.

STATEMENT OF THE CASE

As the district court observed, "[t]he parties agree that the issues to be resolved in this case should be resolved as a matter of law because no genuine issues of material fact exist to be tried." App. 19a. Petitioners Lifestar Ambulance Service, Inc., Coastal Medical Transport, Inc., and Ambulance Services, Inc. are suppliers of ambulance services that furnished services to Medicare beneficiaries during the relevant time frame.[1] App. 13a. Respondents are the Secretary of the Department of Health and Human Services ("DHHS") and related parties responsible for implementation of a fee schedule pursuant to the Balanced

[1] The relevant time frame is the time during which Respondents reimbursed suppliers under the reasonable charge methodology in contravention of Congress's command that a fee schedule rate shall apply to services furnished on or after the effective dates of the statutes. For BBA purposes, the relevant time frame runs from January 1, 2000 through March 31, 2002. For BIPA purposes, the relevant time frame runs from July 1, 2001 through March 31, 2002.

Budget Act of 1997 ("BBA") and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"). App. 13a-14a.

As part of the BBA, Congress passed legislation redefining the way in which ambulance service suppliers are reimbursed for services provided to Medicare beneficiaries. Congress explicitly stated that the changes, which involved the adoption of a fee schedule to replace the old reasonable charge methodology, "shall apply to services furnished on or after January 1, 2000." App. 58a (BBA, Pub. L. No. 105-33, § 4531(b)(3) (1997) (codified in part at 42 U.S.C. § 1395m(l))). But when the DHHS adopted regulations enacting a fee schedule, the regulations only applied the fee schedule to services furnished on or after April 1, 2002. App. 65a (Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services, 67 Fed. Reg. 9100, 9100 (2002) (Feb. 27, 2002) (to be codified at 42 C.F.R. pts. 410 & 414) ("Effective date: April 1, 2002")). **Thus, no fee schedule exists for the relevant time frame.**

In the BIPA, Congress further refined the payment system for ambulance suppliers. Under the old approach, suppliers in certain states did not receive mileage payments for miles traveled in their home county. In the BIPA, Congress directed that in addition to the changes mandated by the BBA, these suppliers should also receive "full payment of any national mileage rate" under the fee schedule for in-county miles. App. 63a (BIPA, Pub. L. No. 106-554, § 423(b)(1) (codified at 42 U.S.C. § 1395m(l)(2)(E))). Congress specifically directed that this amendment "shall apply to services furnished on or after July 1, 2001." App. 63a (*Id.* at § 423(b)(2)). In direct contravention of that

clear congressional mandate, the DHHS adopted a rule that only implemented this change for services furnished on or after April 1, 2002. App. 65a (67 Fed. Reg. 9100, 9100). **Thus, the DHHS has not paid this national mileage rate for in-county miles for services furnished in the relevant time frame.**

Petitioners challenged Respondents' adoption of a regulation that fails to comply with the clear direction of Congress, and Petitioners sought an order from the district court requiring Respondents to adopt and apply a fee schedule for services furnished on or after the dates certain established by Congress in the BBA and the BIPA. App. 13a-14a. The district court denied Respondents' motion to dismiss, finding that it had jurisdiction under the Mandamus Act, 28 U.S.C. § 1361. App. 18a-19a. In doing so, the district court followed every circuit court that had addressed the issue by rejecting Respondents' contention that mandamus is categorically unavailable in cases arising under the Medicare statute. App. 19a n.4.

Having determined that the Medicare Act did not operate as an across-the-board bar to the exercise of mandamus jurisdiction, the court further found it could exercise mandamus jurisdiction[2] even though Petitioners had not pursued administrative relief under the Medicare Act. App. 18a-19a. To avail themselves of the court's mandamus jurisdiction, Petitioners had to show (1) that Respondents owed them a clear, non-discretionary duty and (2) that Petitioners had exhausted all other avenues of

[2] The district court's analysis of mandamus for jurisdictional purposes is intertwined with its analysis of the motions for summary judgment.

relief. App. 20a. On the question of clear non-discretionary duty, the district court found that "the BBA unequivocally required DHHS to develop a new fee schedule applicable to services furnished on or after January 1, 2000." App. 20a. In addition, the court found that "Congress plainly stated in the BIPA that changes in the payment of in-county mileage would apply to services furnished on or after July 1, 2001." App. 20a. The cornerstone of the court's decision was its conclusion that "Congress left no room for DHHS to exercise its discretion to alter the effective dates of these statutory provisions." App. 20a.

Turning to the second prong of mandamus as to whether Petitioners had exhausted other avenues of relief, the court noted that "the question is not simply whether [Petitioners] have completed the administrative process" but is whether "there is another means to obtain adequate review." App. 23a (citing *In re Bethesda Mem'l Hosp., Inc.*, 123 F.3d 1407, 1408 (11th Cir. 1997)). Respondents had insisted that Petitioners must file administrative claims before invoking mandamus jurisdiction, but the district court rejected this contention in light of the fact that the relief sought by Petitioners could not be secured in the administrative process. App. 23a.

Additionally, prior to the announcement of a rule adopting a fee schedule during the relevant time frame, it would have made no sense for Petitioners to mount an administrative challenge, as no fee schedule existed on which to base an administrative claim. App. 24a-25a. The district court recognized that "[n]othing could have been achieved by filing an administrative claim challenging the amounts paid for every service rendered based on the argument that a fee schedule that did not exist would pay them more than the Government had paid." App. 25a.

Finally, the district court noted that Respondents had directed the carriers[3] not to pay any claims for reimbursement under the new, inapplicable fee schedule if the services were furnished prior to April 1, 2002. App. 25a (citing DHHS Program Memorandum Intermediaries/ Carriers). In holding that mandamus jurisdiction was proper, the district court refused to require Petitioners to invoke an administrative process which "(1) is forever incapable of providing the relief they seek, (2) was effectively unavailable to [Petitioners] prior to the announcement of the fee schedule, and (3) is now unavailable to [Petitioners] because of the actions of [Respondents]." App. 26a. Finding no reason to excuse Respondents from their clear, non-discretionary duty to adopt a fee schedule that complied with the effective dates set out by Congress, the district court exercised mandamus jurisdiction and ordered Respondents to adopt a fee schedule that applies to services furnished in the relevant time frame as specified by BBA and BIPA. App. 26a-32a.

Respondents appealed. On April 16, 2004, the United States Court of Appeals for the Eleventh Circuit reversed the district court's denial of the motion to dismiss and remanded with instructions to dismiss for want of subject matter jurisdiction. App. 11a. Petitioners then petitioned the court of appeals for rehearing en banc, and on June 29, 2004, the court of appeals filed an order denying the petition for rehearing and rehearing en banc. App. 44a-45a. This petition for a writ of certiorari followed.

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[3] Intermediaries/carriers are responsible for the actual payment of claims. They are agents of the Secretary.

In reversing on the jurisdictional issue,[4] the Eleventh Circuit panel's opinion focused exclusively on the second prong of the mandamus test: whether an "other adequate remedy is available." Yet, in doing so, the panel never analyzed whether a district court could ever grant Petitioners any relief *besides* mandamus. App. 4a-11a. Relying heavily on *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), a decision addressing only *federal question* jurisdiction and not mandamus jurisdiction, the court of appeals ruled that Petitioners could not meet the test for *mandamus* jurisdiction as an "other adequate remedy" was available – going through the administrative process[5] followed by plenary judicial review under the district court's federal question jurisdiction. App. 8a-9a.

In essence, the court of appeals grafted the federal-question-based "channeling" requirement onto the test for mandamus jurisdiction.[6] App. 10a. In so doing, the Eleventh Circuit ignored the inescapable result that even its suggested "other remedy" would result in a district court

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[4] Because the exercise of mandamus jurisdiction is an issue of law, the standard of review is de novo. App. 4a (citing *Cash v. Barnhart*, 327 F.3d 1252, 1255 n.4 (11th Cir. 2003)).

[5] Respondents acknowledge that an administrative law judge could not have ordered them to modify the effective date of the regulation – the very relief sought by Petitioners. *See* Br. for the Federal Appellants, *filed* 04/29/2003 in the Court of Appeals for the Eleventh Circuit, at 31 ("It is true that an ALJ is obligated to follow current regulations and thus could not compel the Secretary to issue fee schedule regulations or declare invalid those regulations that were in effect."); Defs.' Mem. Law Supp. Defs.' Mot. Dismiss, *filed* 10/22/2002 in the District Court for the Middle District of Georgia, docket entry # 16, at 20 n.10 ("ALJs must, of course, are [sic] bound by applicable DHHS regulations.").

[6] This ruling is in conflict with the holding of every other circuit that has addressed the issue of whether "channeling" is a prerequisite to mandamus jurisdiction. *See* App. 19a n.4 & 4a n.3.

powerless to order Respondents to adopt a fee schedule except through mandamus. As set forth below, the exercise of federal question jurisdiction after "channeling" through the administrative process is not "adequate" because a district court can grant no relief besides mandamus that will result in a fee schedule applicable to the time period mandated by Congress.

SUMMARY OF THE REASONS FOR GRANTING THE WRIT

This appeal involves a significant and pivotal jurisdictional issue that has not been, but should be, settled by this Court – the relationship between the Mandamus Act and the jurisdictional provision in the Medicare Act. This Court has declined to decide on five separate occasions whether 42 U.S.C. § 405 forecloses mandamus jurisdiction, finding it unnecessary to reach the issue in those cases. In this case, however, whether § 405(h) forecloses mandamus jurisdiction is *the* issue to be reviewed and should be settled, once and for all, by this Court.

Prior to the Eleventh Circuit's opinion in this case, nine circuit courts had addressed this issue and uniformly agreed that § 405 does not bar consideration of whether jurisdiction lies under the Mandamus Act. This result follows logically from the fact that the Medicare Act's jurisdiction-limiting provision, 42 U.S.C. § 405 – the provision from which the "channeling" requirement derives – specifically limits federal question jurisdiction *but does not limit mandamus jurisdiction*. The opinion of the Eleventh Circuit, however, effectively forecloses the exercise of mandamus jurisdiction in *all* Medicare cases.

This petition should be granted so that the Court may resolve the otherwise irreconcilable conflict between the Eleventh Circuit and the previously unfractured consensus of nine other circuits, and so that mandamus may be preserved as a viable basis for jurisdiction under the Medicare Act as intended by Congress.

The opinion of the Eleventh Circuit rests on a critical assumption that is then contradicted by the misapplication of this Court's holding in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000). In reversing on the jurisdictional issue, the Eleventh Circuit's opinion focused exclusively on the second prong of the mandamus test – whether an "other adequate remedy" is available. Yet, in doing so, the Eleventh Circuit never analyzed whether a district court could ever grant Petitioners any relief *besides* mandamus. App. 4a-11a. Relying heavily on *Illinois Council*, a decision addressing only *federal question* jurisdiction and not mandamus jurisdiction, the Eleventh Circuit ruled that Petitioners could not meet the test for *mandamus* jurisdiction as an "other adequate remedy" was available – going through the administrative process followed by plenary judicial review under the district court's federal question jurisdiction. App. 8a-9a. The Eleventh Circuit ignored the inescapable result that even its suggested "other remedy" would result in a district court powerless to order Respondents to adopt a fee schedule except through mandamus.

Illinois Council requires "the 'channeling' of virtually all legal attacks through the agency" before *federal question* jurisdiction may be exercised. *Illinois Council*, 529 U.S. at 13. But having misidentified *Illinois Council* as "controlling authority" in a case in which jurisdiction was based upon mandamus, the court of appeals grafted the

federal-question-based "channeling" requirement[7] onto the test for mandamus jurisdiction. App. 10a. This ruling is in conflict with the holding of every other circuit that has addressed the issue of whether "channeling" is a prerequisite to mandamus jurisdiction. *See* App. 19a n.4 & 4a n.3.

Under the Eleventh Circuit's opinion, no claim arising under the Medicare Act could ever meet the test for mandamus jurisdiction. Respondents acknowledge that an administrative law judge could not have ordered them to modify the effective date of the regulation – the very relief sought by Petitioners. *See* Br. for the Federal Appellants, *filed* 04/29/2003 in the Court of Appeals for the Eleventh Circuit, at 31 ("It is true that an ALJ is obligated to follow current regulations and thus could not compel the Secretary to issue fee schedule regulations or declare invalid those regulations that were in effect."); Defs.' Mem. Law Supp. Defs.' Mot. Dismiss, *filed* 10/22/2002 in the District Court for the Middle District of Georgia, docket entry # 16, at 20 n.10 ("ALJs must, of course, are [sic] bound by applicable DHHS regulations."). Moreover, a fee schedule will never materialize unless a district court orders

[7] The Eleventh Circuit's opinion obliterates the distinction between two independent bases of jurisdiction for cases that arise under the Medicare Act: (1) federal question jurisdiction, 28 U.S.C. § 1331, and (2) mandamus jurisdiction, 28 U.S.C. § 1361. Federal question jurisdiction is proper in a case that meets the prerequisites of § 405 of the Medicare Act, which means that such claims must first be "channeled" through the administrative process before federal question jurisdiction can exist. *See* 42 U.S.C. § 405(g) & (h); *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1 (2000). Mandamus jurisdiction, on the other hand, is proper in a Medicare case that meets the prerequisites of the Mandamus Act. 28 U.S.C. § 1361; *see Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 813 (D.C. Cir. 2001); *Ganem v. Heckler*, 746 F.2d 844, 850 (D.C. Cir. 1984) (collecting cases from seven circuits); *Ellis v. Blum*, 643 F.2d 68, 78 (2d Cir. 1981).

Respondents to adopt one, and such an order cannot be made pursuant to the district court's federal question jurisdiction. Mandamus jurisdiction, which exists for the very purpose of allowing courts to hear actions to compel federal officials to follow the law, is the *only* method through which Respondents can be compelled to adopt a fee schedule that applies to the time period specified by Congress.

Despite the uncontested fact that the relief sought by Petitioners could not be obtained administratively and despite the fact that a district court exercising plenary federal question jurisdiction could never grant the relief sought by Petitioners, the court of appeals held that "channeling" was a prerequisite to the exercise of mandamus jurisdiction. *See* App. 10a-11a. That holding – requiring "channeling" as a prerequisite to mandamus jurisdiction in this case despite (a) its inability to provide the relief sought by Petitioners and (b) the fact that the relief sought by Petitioners could only be granted by a district court exercising mandamus jurisdiction – effectively grafts a requirement of "channeling" as a prerequisite to the exercise of mandamus jurisdiction in *all* Medicare cases. Of course, if "channeling" is mandatory for all claims arising under the Medicare Act, then in the Eleventh Circuit[8] no claim arising under the Medicare Act will *ever* satisfy the test for mandamus jurisdiction as an "other adequate remedy" will *always* exist for every such claim. That "remedy" is entirely illusory, however, because neither an administrative law judge nor the district court

[8] The other nine circuits that have addressed this issue have uniformly held that § 405 does not bar consideration of whether jurisdiction is available under the Mandamus Act.

exercising federal question jurisdiction can grant the relief requested – an order requiring Respondents to adopt a fee schedule that applies to services furnished in the relevant time frame as mandated by Congress in the BBA and the BIPA.

This case illustrates the point perfectly. Success for these Petitioners depends completely on Respondents being ordered to comply with the law and to adopt a fee schedule; and, to order the Secretary to adopt a fee schedule, a district court *must* grant *mandamus*. The exercise of federal question jurisdiction[9] after "channeling" through the administrative process is not "adequate" because a district court can grant no relief besides mandamus that will result in a fee schedule applicable to the time period mandated by Congress. The practical effect of the court of appeals ruling places the Eleventh Circuit at odds with nine other circuits by essentially wiping the Mandamus Act off the books for cases arising under the Medicare Act.

Petitioners request that this Court grant their petition for a writ of certiorari to resolve the otherwise irreconcilable conflict between the holding of the Eleventh Circuit and the previously unfractured consensus of nine other circuits which held that 42 U.S.C. § 405(h) does not stand as an obstacle to the exercise of mandamus jurisdiction; and to correct a result that, if undisturbed, will leave untouched the inequities in the payment for ambulance services that Congress sought to correct in the BBA and

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[9] The jurisdictional provision of the Medicare Act, 42 U.S.C. § 405(h), requires the "channeling" of claims through the administrative process prior to the exercise of 28 U.S.C. § 1331 federal question jurisdiction or 28 U.S.C. § 1346 United States defendant jurisdiction.

the BIPA during the legislatively mandated relevant time period.

REASONS FOR GRANTING THE WRIT

I. THE OPINION OF THE ELEVENTH CIRCUIT CONFLICTS WITH THE PREVIOUSLY UNFRACTURED CONSENSUS OF THE NINE OTHER CIRCUITS THAT HAVE ADDRESSED WHETHER 42 U.S.C. § 405(h) FORECLOSES MANDAMUS JURISDICTION.

This appeal involves a significant jurisdictional issue – the relationship between the Mandamus Act and the jurisdictional provision in the Medicare Act – that is, without a doubt, "an important question of federal law that has not been, but should be, settled by this Court." SUP. CT. R. 10(c). By the mid-1980s, this Court had declined to decide, on four different occasions, whether 42 U.S.C. § 405[10] forecloses mandamus jurisdiction. *See Heckler v. Ringer*, 466 U.S. 602, 616 (1984) ("[a]ssuming without deciding that ... § 405(h) does not foreclose mandamus jurisdiction"); *Califano v. Yamasaki*, 442 U.S. 682, 698 (1979); *Mathews v. Eldridge*, 424 U.S. 319, 332 n.12 (1976); *Norton v. Mathews*, 427 U.S. 524, 529-30 (1976). Recently, the Court yet again found it unnecessary to decide this issue when raised by the Secretary. *Your Home Visiting Nursing Servs., Inc. v. Shalala*, 525 U.S.

[10] Section 405 of the Social Security Act is incorporated by reference into the Medicare Act by 42 U.S.C. § 1395ii. App. 48a. While some of these decisions examine § 405 in the context of the Social Security Act, the underlying reasoning on the jurisdictional issue applies equally to either Act.

449, 457 n.3 (1999). In this case, however, whether § 405(h) forecloses mandamus jurisdiction is *the* issue to be reviewed and should be settled, once and for all, by this Court. SUP. CT. R. 10(c).

A simple explanation exists for the Court's finding it unnecessary to address this vital jurisdictional issue: the circuit courts agreed, that is, until the Eleventh Circuit's recent opinion. Before the Eleventh Circuit's opinion in this case, nine circuit courts had addressed this issue and uniformly agreed that § 405 does not bar consideration of whether jurisdiction lies under the Mandamus Act. *See Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 813 (D.C. Cir. 2001) ("virtual unanimity"); *Ganem v. Heckler*, 746 F.2d 844, 850 (D.C. Cir. 1984) (collecting cases from seven circuits and noting "there is now an unfractured consensus in the Courts of Appeals that have considered the question that mandamus remains available under the act in appropriate circumstances"); *Ellis v. Blum*, 643 F.2d 68, 78 (2d Cir. 1981) ("impressive array of cases in this and other circuits has established that § 1361 jurisdiction will lie to review procedures employed in administering [benefits]."); App. 4a n.3 (referencing cases from Second, Third, Fourth, Sixth, Seventh, Eighth, Ninth, Tenth, and D.C. Circuits).

This petition for a writ of certiorari should be granted so that the Court may address whether § 405(h) forecloses mandamus jurisdiction in Medicare cases and thereby resolve the conflict between the holding of the Eleventh Circuit and the previously unanimous holdings of nine other circuits regarding this important jurisdictional issue that "has not been, but should be, settled by this Court." SUP. CT. R. 10(a) & (c).

II. THE ELEVENTH CIRCUIT'S OPINION LOSES THE CRITICAL DISTINCTION BETWEEN MANDAMUS JURISDICTION AND FEDERAL QUESTION JURISDICTION AND MISAPPLIES THIS COURT'S HOLDING IN *SHALALA V. ILLINOIS COUNCIL ON LONG TERM CARE, INC.*, 529 U.S. 1 (2000).

Federal courts have exercised two different types of subject matter jurisdiction in cases that arise under the Medicare Act:[11] (1) federal question jurisdiction, 28 U.S.C. § 1331, and (2) mandamus jurisdiction, 28 U.S.C. § 1361. In Medicare cases, these two types of subject matter jurisdiction are completely independent of one another, are based on two separate jurisdictional statutes, and are, in fact, mutually exclusive. The opinion of the court of appeals, however, obliterates the distinction between these two independent bases of jurisdiction; and, in doing so, the opinion contradicts its own assumption that Mandamus Act jurisdiction can exist in cases arising under the Medicare Act.

Federal question jurisdiction is proper in a Medicare case that meets *the prerequisites of § 405 of the Medicare Act*. *See* 42 U.S.C. § 405(g), (h). This jurisdictional provision requires that for federal question jurisdiction to exist, Medicare claims must first be "channeled" through the administrative process. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1 (2000). "Such claims are subject to plenary judicial review under the Medicare

[11] For purposes of this appeal, Petitioners concede that claims for the creation and application of a fee schedule for payment for ambulance services furnished during the relevant time frame arise under the Medicare Act.

remedial scheme only *after* the administrative review process has been exhausted." App. 8a-9a.

Mandamus jurisdiction, on the other hand, is proper in a Medicare case that meets *the prerequisites of the Mandamus Act.*[12] 28 U.S.C. § 1361. Prior to the Eleventh Circuit's departure, every circuit that had addressed the issue concluded that mandamus jurisdiction can exist over claims arising under the Medicare Act without "channeling" these claims through the administrative process. *See Monmouth Med. Ctr. v. Thompson,* 257 F.3d 807, 813 (D.C. Cir. 2001); *Ganem v. Heckler,* 746 F.2d 844, 850 (D.C. Cir. 1984) (collecting cases from seven circuits); *Ellis v. Blum,* 643 F.2d 68, 78 (2d Cir. 1981); App. 4a n.3 (referencing cases from the D.C., Second, Third, Fourth, Sixth, Seventh, Eighth, Ninth, and Tenth Circuits). This result follows logically from the fact that the Medicare Act's jurisdiction-limiting provision, § 405 – the provision from which the "channeling" requirement derives – specifically limits federal question jurisdiction *but does not limit mandamus jurisdiction*. The distinction makes sense because federal question Medicare cases are claims for payment for covered services, and the administrative process is necessary to create a record that is helpful in the determination of coverage or payment decisions. On the other hand, there is no "channeling" requirement in § 405 as a prerequisite to the exercise of mandamus jurisdiction. The underlying reasoning for this distinction

[12] Mandamus jurisdiction under 28 U.S.C. § 1361 allows courts to hear actions to compel federal officials to follow the law and is proper if (a) the defendant owes the plaintiff a clear, non-discretionary duty, and (b) the plaintiff has no other adequate means of review. *See Heckler v. Ringer*, 466 U.S. 602, 616 (1984); *Cash v. Barnhart,* 327 F.3d 1252, 1258 (11th Cir. 2003). That standard is met here. *See infra* Part III.

is evident from the facts of this case – mandamus jurisdiction is necessary to force a federal agency to adopt the very system that allows Medicare claims to be paid according to the law, and no administrative process or federal question-plenary review can order an agency to follow the law without mandamus.

In short, federal question jurisdiction and mandamus jurisdiction are mutually exclusive in Medicare cases. If a claimant can obtain relief from a district court exercising federal question jurisdiction, then mandamus jurisdiction does not exist because an "other adequate remedy" exists. *See Cash v. Barnhart,* 327 F.3d 1252, 1258 (11th Cir. 2003) (mandamus jurisdiction proper only if "no other adequate remedy is available"). The critical question for this appeal is whether Petitioners had an "other adequate remedy" besides mandamus.

III. PETITIONERS HAVE NO OTHER ADEQUATE REMEDY.

The conclusion that Petitioners had an "other adequate remedy" besides mandamus is error. The court of appeals presumed that Petitioners could have "channeled" their claims through the administrative process and then received the relief they sought from the district court exercising federal question jurisdiction. But this result was, and is, impossible.

Petitioners can only receive the relief they seek through mandamus. Respondents' failure to adopt a regulation that complies with the controlling statute means that no fee schedule exists to pay Petitioners as Congress intended for services furnished during the relevant time frame. A fee schedule for the relevant time

frame will never materialize unless a district court orders Respondents to adopt one. *See* App. 227a (Medicare Program; Notice Of Ambulance Fee Schedule In Accordance With Federal District Court Order, 68 Fed. Reg. 18654 (April 16, 2003) (announcing Respondent's intent to comply with district court's decision)). This order cannot be made pursuant to the district court's federal question authority.[13]

So, assuming an Article III court determined that Petitioners should be paid as Congress intended, how could the court grant this relief? After Petitioners "channeled" their claims through the administrative process, as required by the Eleventh Circuit, what relief could a court grant? **The answer is only mandamus**. A district court could not order Respondents to pay Petitioners damages under its federal question jurisdiction because no fee schedule exists from which to calculate those damages. For Petitioners to be paid as Congress intended, a district court must first order Respondents to adopt a fee schedule applicable to the relevant time frame – *that is mandamus*. There is absolutely no other remedy that will result in a fee schedule during the relevant time frame, therefore no "other adequate remedy" exists and mandamus jurisdiction is proper.

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[13] This is not simply a matter of declaring existing regulations invalid under a district court's federal question jurisdiction – the existing regulations are valid *as to services furnished on or after April 1, 2002*, but the existing regulations do not execute the Congressional directive for the relevant time frame as mandated by Congress in the BBA and the BIPA. In order to compel Respondents to adopt a fee schedule that applies to services furnished on or after the dates certain set forth in the BBA and the BIPA, a district court must exercise mandamus jurisdiction.

The Mandamus Act provides that district courts have original jurisdiction over an action "to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. In determining whether mandamus jurisdiction is proper, the court simply asks whether mandamus relief would be appropriate. *Cash v. Barnhart,* 327 F.3d 1252, 1258 (11th Cir. 2003). Mandamus jurisdiction is appropriate when "(1) the plaintiff has a clear right to the relief requested; (2) the defendant has a clear duty to act; and (3) no other adequate remedy is available."[14] *Id.*; *see also Heckler v. Ringer*, 966 U.S. 602, 616 (1984) (mandamus is "intended to provide a remedy for a plaintiff only if he has exhausted all other avenues of relief and only if the defendant owes him a clear, nondiscretionary duty").

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[14] The court of appeals held that mandamus was not proper because of its conclusion that another adequate remedy is available. While this Court need not address the issue as it is not critical to this appeal, for background purposes Petitioners show the Court that Respondents have breached a clear, non-discretionary duty by adopting a regulation with an effective date that conflicts with the statutory effective dates. As succinctly stated by the district court, the relevant statutory language in "both the BBA and BIPA is unambiguous and expresses the clear intent of Congress that the new fee schedules enacted pursuant to both Acts are to apply to services rendered after a date certain." App. 22a n.7. The amendments of the BBA "shall apply to services furnished on or after January 1, 2000." BBA, Pub. L. No. 105-33, § 4531(b)(3). The BIPA's effective date provision is just as straightforward, stating that the amendment "shall apply to services furnished on or after July 1, 2001." BIPA, Pub. L. No. 106-554, § 423(b)(2). The district court held that "Congress left no room for DHHS to exercise its discretion to alter the effective dates of these statutory provisions." App. 20a. In spite of this language, Respondents adopted a regulation applying fee schedule rates only after April 1, 2002. 67 Fed. Reg. 9100 (Feb. 27, 2002). The statutory duty and the Respondents' breach need no explanation. Indeed, a better example of government action justifying mandamus relief is difficult to imagine.

There is no other adequate means of review to address the single issue of law in this case: should Respondents be compelled to apply a fee schedule (including mileage changes as required by BIPA) to services furnished in the relevant time frame? Respondents wholeheartedly agree that an ALJ lacks the power to address such a claim. *See* Br. for the Federal Appellants, *filed* 04/29/2003 in the Court of Appeals for the Eleventh Circuit, at 31 ("It is true that an ALJ is obligated to follow current regulations and thus could not compel the Secretary to issue fee schedule regulations or declare invalid those regulations that were in effect."); Defs.' Mem. Law Supp. Defs.' Mot. Dismiss, *filed* 10/22/2002 in the District Court for the Middle District of Georgia, docket entry # 16, at 20 n.10 ("ALJs must, of course, are [sic] bound by applicable DHHS regulations."). Mandamus jurisdiction, which exists for the very purpose of allowing courts to hear actions to compel federal officials to follow the law, is the *only* method through which Respondents can be compelled to adopt a fee schedule that applies to the time period specified by Congress. As such, there is no other adequate means of review.

In short, when a federal court orders an agency to follow the law, that is mandamus. 28 U.S.C. § 1361; *see also Nat'l Wildlife Fed'n v. United States,* 626 F.2d 917, 918 n.1 (D.C. Cir. 1980) ("An action purportedly requesting a mandatory injunction against a federal official is properly analyzed as one requesting mandamus."). Because mandamus is the only remedy that can result in payment during the time frame mandated by Congress, there is no "other adequate remedy" besides mandamus. Therefore, mandamus jurisdiction is proper.

IV. THE OPINION ATTEMPTS TO AVOID A CIRCUIT SPLIT BY ASSUMING MANDAMUS JURISDICTION CAN EXIST IN MEDICARE CASES BUT INSTEAD COMPLETELY FORECLOSES MANDAMUS JURISDICTION IN SUCH CASES.

The panel's opinion is internally inconsistent in that it makes a critical assumption that is later flatly contradicted. In a failed attempt to avoid a circuit split, the court of appeals purported to "assume" that the jurisdictional provision applicable to the Medicare Act does not bar mandamus jurisdiction for claims arising under the Medicare statute, specifically stating:

> We assume, without deciding, that mandamus jurisdiction is not barred by 42 U.S.C. § 405(h), and, therefore, is available for a claim arising under the Medicare statute.

App. 4a n.3 (citing cases from the D.C., Second, Third, Fourth, Sixth, Seventh, Eighth, Ninth, and Tenth Circuits). The court's opinion, however, creates a circuit split when it then contradicts that very assumption by effectively ruling that no claim arising under the Medicare Act will ever meet the test for mandamus jurisdiction.

This Court need look no further than the language of 42 U.S.C. § 405(h) to resolve this issue. That jurisdictional provision of the Medicare Act specifically precludes federal question and United States defendant jurisdiction but never mentions the Mandamus Act. 42 U.S.C. § 405(h) ("No action against the United States, the Secretary, or any officer or employee thereof shall be brought under sections 1331 or 1346 of title 28 to recover on any claim arising under this subchapter."). Statutes limiting judicial review only exclude those matters addressed by the

statute. *See Belles v. Schweiker,* 720 F.2d 509, 512 (8th Cir. 1983) (citing *Weinberger v. Salfi*, 422 U.S. 749, 761-62 (1975)). Congress in Section 405 showed that it knows how to cut off jurisdictional avenues; it did just that with federal question and United States defendant jurisdiction. *See Belles*, 720 F.2d at 512 n.4 (finding no clear and convincing evidence that Congress intended to limit mandamus jurisdiction by 405(h)). The fact that Congress did not withdraw jurisdiction under the Mandamus Act in Section 405 shows that Congress intended to leave that option open, and thus mandamus jurisdiction is available in Medicare cases. *See Ganem v. Heckler*, 746 F.2d 844, 852 (D.C. Cir. 1984) ("The fact that Congress knows how to withdraw a particular remedy and has not expressly done so provides some indication of a congressional intent to preserve that remedy."). Moreover, Congress knows how to withdraw *mandamus* act jurisdiction when it so desires to limit judicial review, as that is precisely what it did in Veterans' Affairs cases.[15] *See Ellis v. Blum,* 643 F.2d 68, 81

[15] In response to federal courts exercising judicial review via mandamus in Veterans' Affairs benefits cases, Congress responded by amending 38 U.S.C. § 211(a) to provide that "no other official or any court of the United States shall have the power or jurisdiction to review any such decision *by an action in the nature of mandamus or otherwise.*" *Ellis v. Blum*, 643 F.2d 68, 81 n.14 (2d Cir. 1981) (emphasis supplied to indicate language added by Congress). With respect to section 42 U.S.C. § 405(h), since the early 1980s federal courts have consistently held that section 405(h) does not preclude mandamus jurisdiction. *See, e.g., Ellis v. Blum*, 643 F.2d 68, 82 (2d Cir. 1981); *Belles v. Schweiker*, 720 F.2d 509, 512-13 (8th Cir. 1983); *Colonial Penn Ins. Co. v. Heckler*, 721 F.2d 431, 437 n.2 (3d Cir. 1983) (citing cases in Third Circuit from the late 1970s in which the court exercised mandamus jurisdiction notwithstanding section 405(h)); *City of New York v. Heckler*, 742 F.2d 729, 739 (2d Cir. 1984); *Ganem v. Heckler*, 746 F.2d 844, 850 (D.C. Cir. 1984); *Burnett v. Bowen*, 830 F.2d 731, 736-38 (7th Cir. 1987); *Briggs v. Sullivan*, 886 F.2d 1132, 1142 (9th Cir. 1989). If Congress had intended

(Continued on following page)

n.14 (2d Cir. 1981). Therefore, Section 405(h) provides compelling support for a conclusion that Congress never intended to prevent courts from even considering whether jurisdiction would be proper under the Mandamus Act.

The remainder of the Eleventh Circuit's opinion contravenes its own critical assumption by effectively ruling that no claim arising under the Medicare Act will ever meet the test for mandamus jurisdiction. The court held that Petitioners had an "other adequate remedy" through "administrative review followed by plenary judicial review." App. 10a. Applying the "channeling" requirement derived from § 405, which never mentions mandamus, to a mandamus claim, the opinion concludes that the availability of this "other means to obtain adequate review" precludes mandamus jurisdiction. Since this "other means" of review would apply to all cases arising under the Medicare statute, if the decision of the Eleventh Circuit stands, mandamus is dead in Medicare cases within the Eleventh Circuit – thus directly conflicting with the nine other circuits that have addressed this issue.

The Eleventh Circuit noted that the Medicare statute, as applied in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), "demands the 'channeling' of virtually all legal attacks" through the administrative process before a provider "may seek judicial review." App.

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otherwise, then in response to the decisions of the circuit courts (many of which are now more than 20 years old) Congress would have amended Section 405 to specifically limit mandamus jurisdiction. The fact that Congress has not done so provides further support for the inescapable conclusion that mandamus jurisdiction is not precluded by Section 405(h).

5a. But *Illinois Council* addressed *federal question* jurisdiction, not mandamus. The Eleventh Circuit opinion misses this crucial distinction, effectively ruling that no claim arising under the Medicare Act will ever meet the test for jurisdiction under the Mandamus Act. Grafting the channeling requirement derived from § 405 on to the test for mandamus jurisdiction means that, in the Eleventh Circuit, every claim arising under the Medicare Act must be "channeled" irrespective of the underlying jurisdictional basis asserted by the Petitioners. With "channeling" required for every claim arising under the Medicare statute, then every such claim has an "other adequate remedy" thereby killing mandamus jurisdiction. As the court of appeals stated:

> Mandamus is an extraordinary remedy and will not lie if other remedies are available. Medicare's statutory remedial scheme provides for administrative review followed by plenary judicial review. In the face of this comprehensive statutory scheme, it cannot be said that the second requirement for mandamus review – that there be no alternative avenues of relief – is met.

App. 10a (quotations and internal citation omitted). This conclusion precludes mandamus jurisdiction for every potential claim arising under the Medicare statute, and as such, conflicts with the assumption on which the entire opinion rests, the plain language of § 405(h), and the unanimous opinions of other circuits holding that mandamus jurisdiction is not foreclosed by § 405(h) and can exist in a Medicare case.

Under the unique circumstances of this case, in which Petitioners can only obtain the relief they seek through an order directing a federal official to comply with the law, no

"other remedy" besides mandamus can possibly exist. Even if Petitioners were to "channel" their claims, as the opinion of the Eleventh Circuit requires, after that futile process a district court could not grant them any relief besides mandamus to compel Respondents to follow the law by applying the fee schedule to the relevant time frame.

V. THE COURT OF APPEALS MISUNDERSTOOD THE HOLDING OF THIS COURT IN *HECKLER V. RINGER*, 466 U.S. 602 (1984).

Another significant error in the opinion of the court of appeals warrants the grant of this petition for a writ of certiorari. The court of appeals identified the holding of *Heckler v. Ringer,* 466 U.S. 602 (1984) as follows: "mandamus jurisdiction does not lie merely because resort to the administrative process appears futile." App. 8a. This "holding" supports a critical part of the court of appeals opinion, and the misapplication of this Court's authority warrants the grant of this petition. SUP. CT. R. 10(c).

Ringer involved a classic Medicare Act challenge – determining whether a procedure is medically necessary. The Secretary had issued "instructions to her intermediaries precluding payment" for a specific surgical procedure. *Ringer,* 466 U.S. at 608. After the intermediaries denied coverage, many claimants appealed to ALJs who rendered 170 decisions overruling the intermediaries. *Id.* at 619. The Secretary ultimately adopted a formal ruling binding ALJs, the Appeals Council, and intermediaries. *Id.* at 608. Four plaintiffs challenged this formal ruling, seeking federal question jurisdiction (via § 405) and mandamus jurisdiction.

This Court first considered three plaintiffs[16] who had undergone the surgery prior to the effective date of the formal ruling. The Court ruled that mandamus was inappropriate, as the plaintiffs could not meet two prongs of the test for mandamus jurisdiction.[17] Of significance here, these three plaintiffs had an "other adequate remedy" besides mandamus – the administrative process was granting *full relief* to persons asserting the same claims. *Id.* at 619. The plaintiffs had undergone the surgery *before* the Secretary's formal ruling became binding on the ALJs, and every single challenge to the "instructions to [the] intermediaries" which applied to plaintiffs' claims – 170 of them – had been decided against the Secretary by the ALJs. *Id.* Resort to the administrative process in *Ringer* did not *appear* futile as the court of appeals decision suggests in describing *Ringer's* holding; indeed, the exact opposite is true – in *Ringer*, the administrative process *appeared* to be, and **was**, exactly where to go to get relief.

Seizing on this phantom holding, however, the decision of the court of appeals addresses Petitioners' arguments about the futility of pursuing their claims through the administrative process against the backdrop of decisions involving federal question jurisdiction. App. 4a-11a.

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[16] A fourth plaintiff had not yet had surgery, but the Court found the discussion of mandamus jurisdiction applied equally to his claims. *See Ringer,* 466 U.S. at 620.

[17] The plaintiffs could not point to a clear, non-discretionary duty violated by the Secretary because determining whether a procedure is medically necessary is a discretionary decision. *Ringer,* 466 U.S. at 617 ("The Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision . . . are clearly discretionary decisions."). For this reason alone, mandamus jurisdiction was inappropriate in *Ringer.*

But Petitioners addressed futility only because of a mandamus case in which the plaintiffs had met the jurisdictional test by showing that "all other avenues of relief are either foreclosed or futile." *Monmouth Med. Ctr. v. Thompson,* 257 F.3d 807, 815 (D.C. Cir. 2001).

Petitioners' point was *not* just that they can receive no relief from the administrative process. Petitioners can receive no relief from any tribunal, including a district court, except through mandamus. In contrast with *Ringer*, Petitioners here cannot get relief unless a district court orders Respondents to comply with the law. Petitioners seek the resolution of a single issue – did Congress require Respondents to adopt a fee schedule that shall apply to services furnished on or after January 1, 2000? Respondents admit that an ALJ is powerless to resolve this issue. *See* Br. for the Federal Appellants, *filed* 04/29/2003 in the Court of Appeals for the Eleventh Circuit, at 31 ("It is true that an ALJ is obligated to follow current regulations and thus could not compel the Secretary to issue fee schedule regulations or declare invalid those regulations that were in effect."). This is true because ALJs address claims for entitlement to benefits. Here, the claims potentially impacted by an order compelling Respondents to adopt and apply a fee schedule have all been submitted, considered, approved, and paid (under the Congressionally-discarded reasonable charge system). The only remaining issue is whether those claims should have been paid under a fee schedule, and that issue is the same for every supplier who had claims conclusively approved under the old reasonable charge system. No federal question relief could possibly be granted to any claimant without a fee schedule in place, and no fee schedule will ever exist without an

order directing Respondents to adopt one. No relief exists but mandamus.

CONCLUSION

The petition for a writ of certiorari should be granted. Review of the court of appeals decision is needed so that the Court may address the significant jurisdictional issue regarding the relationship between 42 U.S.C. § 405(h) and 28 U.S.C. § 1361; and, in doing so, thereby resolve the conflict between the Eleventh Circuit and the nine other circuits that have addressed this issue by holding that § 405(h) does not bar consideration of whether mandamus jurisdiction exists.

Respectfuly submitted,

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365 F.3d 1293

United States Court of Appeals,
Eleventh Circuit.

LIFESTAR AMBULANCE SERVICE, INC., a Georgia corporation, individually and on behalf of a class of all entities similarly situated, Coastal Medical Transport, Inc., a North Carolina corporation, individually and on behalf of a class of all entities similarly situated, Ambulance Services, Inc., a Tennessee corporation, individually and on behalf of a class of all entities similarly situated, Plaintiffs-Appellees,

v.

UNITED STATES of America, Department of Health and Human Services, Tommy Thompson, in his official capacity as Secretary/Director of D.H.H.S., Health Care Financing Administration (Centers for Medicare & Medicaid Services), Thomas A. Scully, in his official capacity as Secretary/Director of H.C.F.A./C.M.S., Defendants-Appellants.

No. 03-11392.

April 16, 2004.

Jeffrey A. Clair, Washington, DC, for Defendants-Appellants.

James E. Butler, Jr., Dustin Thomas Brown, Jason L. Crawford, James Clay Fuller, Butler, Wooten, Overby & Cheeley, Columbus, GA, G. Christopher Kelly, Atlanta, GA, for Plaintiffs-Appellees.

Appeal from the United States District Court for the Middle District of Georgia.

Before *ANDERSON, BLACK* and *HILL*, Circuit Judges.

HILL, Circuit Judge:

This case arises from a dispute over the Medicare reimbursement rates for ambulance service suppliers. The district court denied defendants' motion to dismiss for want of mandamus jurisdiction, entered summary judgment on the merits for plaintiffs, and certified them as a class. Defendants timely filed this appeal.

I.

Plaintiffs are ambulance suppliers based in Georgia, North Carolina, and Tennessee, who provide ambulance services to Medicare recipients. They seek to bring a class action against the Department of Health and Human Services ("DHHS"), the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), and individuals associated with those entities. Plaintiffs allege that the federal defendants failed to comply with the Balanced Budget Act of 1997 ("BBA"), requiring them to establish by January 1, 2000, a national fee schedule for payment of ambulance services. Pub.L. No. 105-33, § 4531(b), 111 Stat. 451 (1997), codified at 42 U.S.C. § 1395m(1). They also allege that DHHS has failed to timely implement certain mileage fee schedules as required by the Medicare, Medicaid and SCHIOP Benefits Improvement and Protection Act of 2000 ("BIPA"). Plaintiffs seek injunctive relief in the form of a writ of mandamus ordering DHHS to adopt fee schedules that comply

with those mandates, and to apply them retroactively to services provided from January 1, 2000 forward.[1]

The federal defendants moved to dismiss this action on the basis that plaintiffs failed to exhaust their administrative remedies as required by the Medicare Act. *See* 42 U.S.C. § 1395ff(b) and 42 U.S.C. § 1395ii. Both parties also filed cross-motions for summary judgment on the merits.

The district court denied the motion to dismiss, holding that the mandamus jurisdiction invoked by plaintiffs under 28 U.S.C. § 1361 is both available and appropriate in this case, thereby obviating the necessity for them to exhaust their claims administratively. The court then entered summary judgment for plaintiffs on the merits of their claim, issuing a writ of mandamus to the Secretary of Health and Human Services (the "Secretary") to implement a fee schedule for the relevant time period, and certifying a class of ambulance providers.[2]

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[1] Because we do not reach the merits of this case, we do not consider how the federal defendants might be ordered to comply with a statutory mandate (budget neutrality) now impossible to meet.

[2] The district court questioned why it should certify a class since the relief sought would be obtained by individual plaintiffs applying for payment under the rate schedule ordered by the court to be implemented by the DHHS with recourse to administrative review in the event of disputes. Apparently, however, the court adopted the plaintiffs' argument that the implementation of the retroactive fee schedule would "create an entitlement to a substantial fund" and that it could "retain jurisdiction to determine whether [DHHS] complied with the Court's order." The court also noted the relevance of the certification to the issue of attorneys' fees, stating "I understand that down the road, if the plaintiffs' counsel has produced a substantial result, then you still get paid, presumably, even if there's not a big damage award that the Court has to divvy up." R.E. 32-34.

The threshold issue we must decide is whether the district court correctly assumed mandamus jurisdiction over this action, since, in the absence of subject-matter jurisdiction, we may not proceed. We review the district court's determination that it had mandamus jurisdiction under 28 U.S.C. § 1361 *de novo. Cash v. Barnhart,* 327 F.3d 1252, 1255 n. 4 (11th Cir. 2003).

II.

Mandamus jurisdiction is appropriate[3] only where (1) the defendant owes a clear nondiscretionary duty to the plaintiff and (2) the plaintiff has exhausted all other avenues of relief. *Heckler v. Ringer,* 466 U.S. 602, 615, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984). The district court held that plaintiffs satisfied both of these preconditions for invoking mandamus jurisdiction under Section 1361. We disagree.

Plaintiffs cannot invoke the extraordinary remedy of mandamus because they have an alternative "avenue of relief." *Mallard v. U.S. District Court,* 490 U.S. 296, 309, 109 S.Ct. 1814, 104 L.Ed.2d 318 (1989). The Medicare Act establishes a comprehensive remedial scheme, providing

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[3] We assume, without deciding, that mandamus jurisdiction is not barred by 42 U.S.C. § 405(h) and, therefore, is available for a claim arising under the Medicare statute. *See Buchanan v. Apfel,* 249 F.3d 485, 491-92 (6th Cir. 2001); *Cordoba v. Massanari,* 256 F.3d 1044, 1047 (10th Cir. 2001); *Monmouth Med. Ctr. v. Thompson,* 257 F.3d 807, 813 (D.C. Cir. 2001); *United States ex rel. Rahman v. Oncology Associates, P.C.,* 198 F.3d 502, 515 (4th Cir. 1999); *Briggs v. Sullivan,* 886 F.2d 1132, 1142 (9th Cir. 1989); *Burnett v. Bowen,* 830 F.2d 731, 736-38 (7th Cir. 1987); *City of New York v. Heckler,* 742 F.2d 729, 739 (2d Cir. 1984); *Belles v. Schweiker,* 720 F.2d 509, 512-13 (8th Cir. 1983); *Colonial Penn Ins. Co. v. Heckler,* 721 F.2d 431, 437 n. 2 (3d Cir. 1983).

both administrative hearing rights for aggrieved providers, such as plaintiffs, and judicial review of the Secretary's final decisions. *Ringer,* 466 U.S. at 605-06 and n. 1, 104 S.Ct. 2013 (quoting 42 U.S.C. § 405(g)). The Supreme Court has made clear that "[o]rdinarily mandamus may not be resorted to as a mode of review where a statutory method of appeal has been prescribed." *Roche v. Evaporated Milk Ass'n,* 319 U.S. 21, 27-28, 63 S.Ct. 938, 87 L.Ed. 1185 (1943).

It is undisputed that plaintiffs did not resort to these administrative remedies. They filed no claim with DHHS for payment under the fee schedule required by the BBA and BIPA. Plaintiffs contend, however, and the district court agreed, that Medicare's administrative remedies were "realistically [un]available" to plaintiffs because "the relief sought by the Plaintiffs in this case could not be secured in the administrative process."[4] The government's suggestion to the contrary, the court concluded, "ignores reality."

The reality, however, is that the Medicare statute "demands the 'channeling' of virtually all legal attacks through the [DHHS]" before a health care provider may seek judicial review of a claim arising under the Medicare statute. *Shalala v. Illinois Council on Long Term Care,* 529 U.S. 1, 13, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000).[5] This

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[4] Plaintiffs argued that, because no ALJ could compel the Secretary to alter the effective date of the fee schedule regulations, resort to Medicare's administrative review procedures would be futile.

[5] Although the exhaustion requirement may be waived, *see Mathews v. Eldridge,* 424 U.S. 319, 330-32 & n. 11, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976), plaintiffs cannot meet any of the three requirements for waiver, including that they show irreparable injury if forced to exhaust. *See Sampson v. Murray,* 415 U.S. 61, 90-91, 94 S.Ct. 937, 39

(Continued on following page)

"nearly absolute channeling requirement" serves important governmental interests in administrative efficiency and judicial economy, and "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." *Id.* at 2, 120 S.Ct. 1084.

Nor is Medicare's statutory exhaustion requirement subject to judge-made exceptions on a case by case basis when a particular court might find the requirement too burdensome or futile. *Id.* at 2, 120 S.Ct. 1084 (405[h]'s bar "reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies' . . . by preventing the application of exceptions to those doctrines"). As we noted in *Cochran v. U.S. Health Care Financing Admin.*, 291 F.3d 775, 780 (11th Cir. 2002):

> It is true that in some contexts, administrative exhaustion requirements are tempered by judge-made exceptions, chief among which are that exhaustion of administrative remedies sometimes is not required if resort to them would be futile, or if the remedy they offer is inadequate. Those judge-made exceptions do not apply, however, to a statutorily-mandated exhaustion requirement like [Medicare's].

See also Alexander v. Hawk, 159 F.3d 1321, 1326 (11th Cir. 1998) ("Mandatory exhaustion is not satisfied by a judicial conclusion that the requirement need not apply").

Ultimately, the issue in this case is whether the claim of mandamus jurisdiction accomplishes the nullification of Medicare's exhaustion requirement by permitting plaintiffs

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L.Ed.2d 166 (1974) (recoverable monetary loss does not constitute irreparable injury).

to argue that they have no other avenue of relief because resort to administrative remedies is "futile." Thus, under the authority of mandamus, the doctrine of judge-made exceptions to administrative exhaustion is resurrected.[6]

Plaintiffs' view of the propriety of mandamus jurisdiction is that it is directly related to the likelihood that they will prevail administratively. In their view, as the likelihood that they will prevail before the administrative hearing officer goes down, the requirement that they appear before him also diminishes. Because no hearing officer could compel the Secretary to issue new fee schedule regulations or declare invalid the regulations in effect now, plaintiffs characterize their chances for administrative relief as "hopeless." This leads them to conclude that their administrative remedies are "inadequate," thus entitling them to invoke the district court's mandamus jurisdiction. It is not the *availability* of the administrative avenue of relief that figures prominently in their calculation of its impact on mandamus jurisdiction, but rather the *attractiveness* of it in comparison to mandamus jurisdiction.[7]

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[6] This would be so at least where plaintiff's right to relief is clear.

[7] We have reviewed the record and find no support for plaintiffs' contentions that the Secretary barred them from challenging implementation of the fee schedule provisions in the administrative process. The manual provision to which they cite was addresses [sic] only to the agency's carriers and intermediaries, i.e., to the agency's initial claims processors, not to the agency's ALJ's. It did not preclude any plaintiff from arguing, in an administrative appeal from an initial payment decision, that the Secretary had an obligation to promulgate and apply a fee schedule. Nor did it prevent individual plaintiffs from submitting fee schedule claims in the administrative process; some who did so obtained relief similar to that sought by plaintiffs here. *See Highlander Ambulance,* Adm. Docket No. 999-17-9983 (July 16, 2002).

This calculus was rejected by the Supreme Court twenty years ago when it held that mandamus jurisdiction does not lie merely because resort to the administrative process appears futile. *Ringer,* 466 U.S. at 616-17, 104 S.Ct. 2013. In *Ringer,* the Secretary had issued a formal ruling holding that a particular surgical procedure was still experimental and thus could not be covered by Medicare. This ruling was binding upon the administrative hearing officers, and, thus, the *Ringer* plaintiffs contended that administratively contesting the denial of coverage was futile. They concluded that mandamus relief was, therefore, permissible because they had no "alternative avenue of relief."

The Court rejected this argument, holding that alleged limitations on the remedial powers of the hearing officers does not render Medicare's administrative remedies a nullity. *Id.* at 616-17. The Court held that the plaintiffs there "clearly have an adequate remedy" under Medicare, including administrative hearing and juridical review of any adverse final decision rendered for *whatever* reason. *Id.* The Court concluded that no writ of mandamus could properly issue because mandamus "is intended to provide a remedy for a plaintiff only if he has exhausted all other avenues of relief." *Id.* at 616.

The Supreme Court has recently reaffirmed the immunity of Medicare's exhaustion requirement to the allegation of futility. *Illinois Council,* 529 U.S. at 2, 120 S.Ct. 1084. In *Illinois Council,* the Court held that, despite the fact that some claims, such as constitutional or statutory challenges, cannot be resolved administratively, they must still proceed first through the administrative process. 529 U.S. at 23-24, 120 S.Ct. 1084. Such claims are subject to plenary judicial review under the Medicare

remedial scheme only *after* the administrative review process has been exhausted. *Id.* As the Court concluded:

> The fact that the agency might not provide a hearing for that *particular contention,* or may lack the power to provide one . . . is beside the point because it is the "action" arising under the Medicare Act that must be channeled through the agency. After the action has been so channeled, the court will consider the contention when it later reviews the action. And a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide, including, where necessary, the authority to develop an evidentiary record.

Id. (internal citations and quotations omitted). *Illinois Council,* thus, expressly holds that the vitality of the exhaustion requirement is not vitiated by statutory claims that cannot be resolved initially at the administrative level. *Id.*

Illinois Council teaches the importance of distinguishing between administrative *relief* and an administrative *remedy.* The fact that plaintiffs may not be able to secure the relief they seek at the administrative hearing stage of their claim does not mean that the Act's remedial structure, which includes plenary judicial review, does not provide an adequate remedy. *Id.* Plaintiffs have cited no case, and we know of none, that says that a statutory avenue of review may be deemed "inadequate" for purposes of invoking mandamus jurisdiction merely because full relief must await judicial review of a final administrative decision.

To ensure that mandamus remains an extraordinary form of relief and not a strategy for avoiding administrative exhaustion, plaintiffs must clearly demonstrate that they have no alternative means to obtain the relief they seek. *Mallard,* 490 U.S. at 309, 109 S.Ct. 1814. Here all plaintiffs have shown is that they are unlikely to win their preferred relief at the preliminary, administrative stage of an otherwise adequate remedy.[8]

Exhaustion of administrative remedies, however, is not a strategic option, but rather a statutory requirement. Mandamus does not lie, as plaintiffs assert, merely because "the administrative process is fundamentally ill equipped to resolve this claim."

"Mandamus is an extraordinary remedy and will not lie if other remedies are available." *In re United States,* 985 F.2d 510, 511 (11th Cir. 1993). Medicare's statutory remedial scheme provides for administrative review followed by plenary judicial review. In the face of this comprehensive statutory scheme, it cannot be said that the second requirement for mandamus review – that there be no alternative avenues of relief – is met.

Both *Ringer* and *Illinois Council* make clear that the fact that an agency's administrative review, by itself, might not afford the relief claimed, does not excuse the jurisdictional requirements of presentment and exhaustion of administrative remedies. The administrative review provided by Medicare's administrative hearing

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[8] The fact that an alternative to "busting the budget," an outcome the district court acknowledged might result from its injunction, may be worked out during the administrative process is one of the governmental interests underlying the statutory requirement for exhaustion.

officers is but the first step in a comprehensive statutory remedial scheme that fully empowers a reviewing court to consider and remedy any of the violations of law alleged by plaintiff here. In view of the controlling authority that postponement of judicial review does not amount to a preclusion of review, plaintiffs may not avail themselves of mandamus jurisdiction where there is "another means to obtain adequate review." Therefore, we hold that the district court did not have mandamus jurisdiction and shall reverse the district court's entry of judgment under that authority.

III.

The denial of the motion to dismiss is REVERSED and the judgment of the district court is VACATED. This case is remanded with instructions to dismiss for want of subject-matter jurisdiction.

211 F.R.D. 688

United States District Court,
M.D. Georgia,
Columbus Division.

LIFESTAR AMBULANCE SERVICE, INC., individually and on behalf of a class of all entities similarly situated; Coastal Medical Transport, Inc., individually and on behalf of a class of all entities similarly situated; Ambulance Services, Inc., individually and on behalf of a class of all entities similarly situated, Plaintiffs,

v.

UNITED STATES of America; the Department of Health and Human Services; Tommy Thompson in his official capacity as Secretary/Director of DHHS; the Health Care Financing Administration (Centers for Medicare & Medicaid Services); and Thomas A. Scully in his official capacity as Secretary/Director of HCFA/CMS, Defendants.

No. 4:02-CV-127-1(CDL).

Jan. 16, 2003.

Marlan B. Wilbanks, G. Christopher Kelly, Atlanta, GA, *James E. Butler, Jr.*, James Clay Fuller, *Dustin T. Brown*, Columbus, GA, Jason Lance Crawford, Columbus, GA, *Jonathan H. Waller*, Birmingham, AL, for plaintiffs.

Daniel Bensing, *Sheila Lieber*, Federal Programs Branch, Washington, DC, *Brendan F. Flanagan*, Columbus, GA, for defendants.

ORDER

LAND, District Judge.

The Court presently has pending before it Defendants' Motion to Dismiss, Defendants' Motion for Summary

Judgment, Plaintiffs' Motion for Summary Judgment, and Plaintiffs' Motion for Class Certification. These motions have been fully briefed and argued by the parties. The Court finds that it has subject matter jurisdiction of this case and that Plaintiffs are entitled to a writ of mandamus as a matter of law. Accordingly, Defendants' Motion to Dismiss and Motion for Summary Judgment are denied, and Plaintiffs' Motion for Summary Judgment is granted in part.[1] The Court also finds that a Rule 23(b)(2) class should be certified, and therefore, Plaintiffs' Motion for Class Certification is granted.

I. FACTUAL BACKGROUND

This case arises from a dispute over the Medicare reimbursement rates for ambulance service suppliers. The named Plaintiffs, three ambulance suppliers based in Georgia, North Carolina, and Tennessee who provide ambulance services to Medicare recipients, bring this putative class action against the Department of Health and Human Services ("DHHS"), the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), and individuals associated with those entities. Plaintiffs' Complaint focuses upon Defendants' alleged failure to comply with congressional mandates establishing the effective dates for certain fee schedules.

Plaintiffs contend that DHHS ignored the clear direction of Congress, as expressed in the Balanced

[1] Plaintiff's Motion for Summary Judgment, as originally filed, requested the Court to find that they were entitled to payment under a lawful fee schedule – in other words, Plaintiffs sought damages and not merely injunctive relief. At this time, Plaintiffs do not assert a claim for damages but only seek declaratory and mandamus relief.

Budget Act of 1997 ("BBA"), by failing to adopt a fee schedule applying to ambulance services furnished from January 1, 2000, through March 31, 2002. Plaintiffs also maintain that DHHS has failed to properly implement certain mileage fee schedules applicable to services provided from July 1, 2001, through March 31, 2002, as required by the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"). Plaintiffs seek injunctive relief ordering DHHS to adopt a fee schedule covering ambulance services supplied to Medicare recipients as described in the BBA and a fee schedule for mileage as required by the BIPA during the time periods just described.

The Medicare Act, 42 U.S.C. § 1395 *et seq.*, creates a health insurance program for elderly and disabled individuals. The program is administered by the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), on behalf of the Secretary of DHHS, who is ultimately responsible for the program. Medicare Part A authorizes payments for covered inpatient hospital treatment and related services, including skilled nursing home care. Part B, which is applicable in this case, authorizes payment for covered items and services provided to individuals such as physicians' treatment, clinical laboratory tests, or durable medical equipment. Part B also covers and pays for ambulance services, including those provided by ambulance service suppliers like Plaintiffs. *See e.g.*, Supplementary Medical Insurance (SMI) Benefits, 42 C.F.R. § 410.10(i) (2001). Plaintiffs contend that Congress specified a time frame during which payments for services furnished to Medicare patients and for certain mileage should be paid in accordance with the fee schedule provisions of the BBA and BIPA.

Plaintiffs further contend that DHHS failed to use the appropriate fee schedule in making payments during that period contrary to the expressed intention of Congress. To fully understand Plaintiffs' claims, a brief review of the evolution of the methodology for reimbursing ambulance suppliers under the Medicare Act is helpful.

A. Methodology Prior to the Adoption of the BBA

Traditionally, Medicare paid for ambulance services furnished by suppliers on a "reasonable charge" basis. *See Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services*, 65 Fed.Reg. 55,078, 55,078 (proposed Sept. 12, 2000) (to be codified at 42 C.F.R. pts. 410 & 414). A "reasonable charge" for ambulance services is determined by the lowest of the customary, prevailing, actual, or inflation indexed charges. *Id.* Under the "reasonable charge" methodology, different billing and payment methods were in use in different localities. Some methods provided separate charges for items such as individual services, mileage, and supplies. In contrast, one method provided a single, all-inclusive charge for all services, mileage, and supplies. *Id.*

B. Fee Schedule Under BBA Effective January 1, 2000

In 1997, as part of the BBA, Congress mandated the establishment of a "national" ambulance fee schedule for ambulance services to be paid for under Medicare. Congress required that the fee schedule create more equitable payments for similar services performed in different locations and that it be designed to replace the previous

"reasonable charge" methodology. In enacting the BBA, Congress explicitly provided that the fee schedule adopted by DHHS "*shall apply to services furnished on or after January 1, 2000.*" Pub.L. No. 105-33, § 4531(b)(2) & (3) (codified in part at 42 U.S.C. § 1395m(1)) (emphasis added).

Pursuant to the BBA, DHHS adopted a fee schedule on February 27, 2002, but applied it only to services furnished on or after April 1, 2002, over two years after the effective date mandated by Congress. *See generally Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services*, 67 Fed.Reg. 9,100, 9,100 (Feb. 27, 2002) (to be codified at 42 C.F.R. pts. 410 & 414). Plaintiffs contend that they, along with the other members of the putative class, are entitled to have a fee schedule implemented that applies to services furnished from January 1, 2000, to March 31, 2002, under the terms of the BBA.[2] Thus, they seek injunctive relief ordering Defendants to implement such a fee schedule.

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[2] Plaintiffs, apparently recognizing that DHHS has some discretion in developing the fee schedule, do not seek an order requiring DHHS to apply retroactively the fee schedule it implemented for services supplied on or after April 1, 2002. Plaintiffs simply seek an order requiring Defendants to adopt a fee schedule covering the period January 1, 2000, through March 31, 2002, as mandated by the BBA. Presumably, if Defendants implemented a fee schedule that failed to comply with the Court's order and/or the intent of Congress, Plaintiffs would seek further relief from the Court at the appropriate time.

C. BIPA Change in Payment of In-County Miles

In addition to the changes in reimbursement fee schedules enacted as part of the BBA, Congress also addressed inequities inherent in compensating ambulance suppliers under the reasonable charge methodology by enacting the BIPA in 2000. Pub.L. No. 106-554, § 423(b)(2), 114 Stat. 2763 (codified in part at 42 U.S.C. § 1395m(1)(2)(E) (2000)). The BIPA provided, in relevant part, that certain ambulance suppliers that had previously not received mileage payments for miles traveled in their home county should begin receiving compensation for those miles. 42 U.S.C. § 1395m(1)(2)(E). Congress made this provision *applicable to services furnished on or after July 1, 2001.* Medicaid, Medicare and SCHIP Benefits Improvement and Protection Act of 2000 § 423(b)(2). These mileage reimbursement changes only applied to certain states, including Tennessee and North Carolina, the homes of two of the named Plaintiffs in this litigation – Ambulance Transport Services, Inc. and Coastal Medical Transport, Inc., respectively. Notwithstanding the clear congressional mandate that the mileage provisions of the BIPA be applied to services furnished on or after July 1, 2001, DHHS adopted a fee schedule and applied it only to services furnished on or after April 1, 2002. Therefore, Plaintiffs Ambulance Transport Services, Inc. of Tennessee and Coastal Medical Transport, Inc. of North Carolina, along with others similarly situated, were not paid for mileage traveled in their home counties as required by the BIPA for the period July 1, 2001, through March 31, 2002. These Plaintiffs seek injunctive relief requiring that Defendants implement the BIPA mileage provisions to apply to services provided between July 1, 2001, and March 31, 2002, as required by the BIPA.

II. DISCUSSION

A. Defendants' Motion to Dismiss

Defendants preliminarily move to dismiss Plaintiffs' Complaint for lack of subject matter jurisdiction on the basis that Plaintiffs have failed to exhaust their administrative remedies under the Medicare Act.[3] It is undisputed that Plaintiffs have not availed themselves of any of the administrative remedies provided for under the Medicare Act. Plaintiffs contend that their claims do not "arise under" the Medicare Act but instead arise under the BBA and BIPA, and therefore, the Medicare Act's exhaustion of remedies requirement is not applicable. Plaintiffs alternatively argue that the Medicare Act's exhaustion of remedies requirement has no application to their claim for mandamus relief.

Pretermitting whether Plaintiffs' claims "arise under" the Medicare Act, the Court finds that given the unique circumstances of this case, Plaintiffs' claim for mandamus relief does not require them to exhaust administrative remedies provided for under the Medicare Act. *See* 28 U.S.C. § 1361 ("The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff."). Unlike other forms of subject matter jurisdiction, mandamus relief under § 1361 is not explicitly excluded from judicial review by § 405(h) of the Medicare Act. Consequently, Plaintiffs' failure to exhaust administrative

[3] Section 405(h) of the Medicare Act precludes federal court jurisdiction for claims "arising under the Act," until the aggrieved party has exhausted its administrative remedies. 42 U.S.C. § 405(h).

remedies under the Medicare Act does not deprive the Court of subject matter jurisdiction over Plaintiffs' mandamus claims.[4] Accordingly, Defendants' Motion to Dismiss based upon lack of subject matter jurisdiction is denied.[5]

B. The Parties' Motions for Summary Judgment

The parties agree that the issues to be resolved in this case should be resolved as a matter of law because no genuine issues of material fact exist to be tried. Accordingly, summary judgment is the appropriate procedural vehicle for deciding this case. *See* Fed.R.Civ.P. 56(c). The issue presented is whether Plaintiffs or Defendants are entitled to judgment as a matter of law on Plaintiffs' mandamus claim. Mandamus is an extraordinary equitable remedy that requires a substantial showing by the plaintiff. As the Eleventh Circuit has stated, "Mandamus

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[4] The Court acknowledges that the Eleventh Circuit has not yet addressed this issue. However, several other circuits have found mandamus jurisdiction appropriate in cases involving claims ostensibly governed by 42 U.S.C. § 405(h), noting that mandamus jurisdiction is not listed among the other forms of subject matter jurisdiction specifically precluded absent exhaustion of administrative remedies. *See Buchanan v. Apfel,* 249 F.3d 485, 491-92 (6th Cir. 2001); *Cordoba v. Massanari,* 256 F.3d 1044, 1047 (10th Cir. 2001); *Monmouth Med. Ctr. v. Thompson,* 257 F.3d 807, 813 (D.C. Cir. 2001); *United States ex rel. Rahman v. Oncology Assocs., P.C.,* 198 F.3d 502, 515 (4th Cir. 1999); *Briggs v. Sullivan,* 886 F.2d 1132, 1142 (9th Cir. 1989); *Burnett v. Bowen,* 830 F.2d 731, 736-38 (7th Cir. 1987); *City of New York v. Heckler,* 742 F.2d 729, 739 (2d Cir. 1984); *Ganem v. Heckler,* 746 F.2d 844, 850-52 (D.C. Cir. 1984); *Belles v. Schweiker,* 720 F.2d 509, 512-13 (8th Cir. 1983); *Colonial Penn Ins. Co. v. Heckler,* 721 F.2d 431, 437 n. 2 (3d Cir. 1983); *Ellis v. Blum,* 643 F.2d 68, 82 (2d Cir. 1981).

[5] Insofar as Defendants seek to dismiss Plaintiffs' Complaint on non-jurisdictional grounds, Defendants' Motion to Dismiss is denied for the same reasons that Defendants' Motion for Summary Judgment is denied. *See infra* Part B.

is an extraordinary remedy and will not lie if other remedies are available." *In re United States,* 985 F.2d 510, 511 (11th Cir. 1993); *see also George Kabeller, Inc. v. Busey,* 999 F.2d 1417, 1423 (11th Cir. 1993); *Dist. Lodge No. 166, Int'l Assoc. of Machinists and Aerospace Workers, AFL-CIO v. TWA Servs., Inc.,* 731 F.2d 711, 717 (11th Cir. 1984). Mandamus relief is appropriate when (1) the defendant owes a clear nondiscretionary duty to the plaintiff and (2) the plaintiff has exhausted all other avenues of relief. *Heckler v. Ringer,* 466 U.S. 602, 616, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984).

1. Nondiscretionary Duty

The Court finds that the BBA unequivocally required DHHS to develop a new fee schedule applicable to services furnished on or after January 1, 2000. Balanced Budget Act of 1997, Pub.L. No. 105-33, § 4531(b)(2) & (3), 111 Stat. 451 (1997) (codified in part at 42 U.S.C. § 1395m(1)). The Court also finds that Congress plainly stated in the BIPA that changes in the payment of in-county mileage would apply to services furnished on or after July 1, 2001. Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, Pub.L. No. 106-554, § 423(b)(2), 114 Stat. 2763 (codified in part at 42 U.S.C. § 1395m(1)(2)(E) (2000)). Congress left no room for DHHS to exercise its discretion to alter the effective dates of these statutory provisions. When an executive agency or department is charged with implementing a congressional enactment through the regulatory process and Congress' intent is clear, no room for interpretation exists. No excuses allow the agency to avoid compliance. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.,* 467 U.S. 837, 842-43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984) ("If the intent of Congress is clear,

that is the end of the matter; for the Court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). In both the BBA and BIPA, the intent of Congress is clear: a fee schedule for ambulance services "*shall* apply to services furnished on or after January 1, 2000," and a fee schedule for in-county mileage "*shall* apply to services furnished on or after July 1, 2001." Balanced Budget Act of 1997, § 4531(b)(3); Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act, § 423(b)(2). "[T]hat is the end of the matter." *Chevron,* 467 U.S. at 842-43, 104 S.Ct. 2778[6]

Notwithstanding this clear nondiscretionary duty to follow the law and develop a fee schedule applicable to services provided subsequent to January 1, 2000, DHHS ignored the congressional mandate and promulgated a fee schedule to apply to services furnished on or after April 1, 2002. *See Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services*, 67 Fed.Reg. at 9,100. DHHS likewise ignored Congress' mandate that the in-county mileage changes provided by the BIPA be applied for services furnished after July 1, 2001, and instead unilaterally made the fee schedule effective for services provided on or after April 1, 2002. *See id.*

DHHS simply does not have the authority to legislate an effective date different than that provided by Congress.

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[6] *See Lexecon, Inc. v. Milberg Weiss Bersh[illegible]d Hynes & Lerach,* 523 U.S. 26, 35, 118 S.Ct. 956, 140 L.Ed.2d 62 (1998) ("[T]he mandatory 'shall,' ... normally creates an obligation impervious to judicial discretion.") (citing *Anderson v. Y[illegible]gkau,* 329 U.S. 482, 483, 67 S.Ct. 428, 91 L.Ed. 436 (1947)).

The rule-making power granted to an administrative agency charged with the administration of a federal statute is not the power to make law. Rather, it is the power to adopt regulations to carry into effect the will of Congress. *Ernst & Ernst v. Hochfelder,* 425 U.S. 185, 213-14, 96 S.Ct. 1375, 47 L.Ed.2d 668 (1976); *Dixon v. United States,* 381 U.S. 68, 74, 85 S.Ct. 1301, 14 L.Ed.2d 223 (1965); *Manhattan Gen. Equip. Co. v. Comm'r,* 297 U.S. 129, 134, 56 S.Ct. 397, 80 L.Ed. 528 (1936). Regulations must "be consistent with the statute under which they are promulgated." *United States v. Larionoff,* 431 U.S. 864, 873, 97 S.Ct. 2150, 53 L.Ed.2d 48 (1977). An administrative regulation that fails to carry into effect the will of Congress, and instead operates to void or repeal the express terms of the statute, is a nullity. *Dixon,* 381 U.S. at 74, 85 S.Ct. 1301. Because the effective dates for the fee schedules promulgated by DHHS flatly contradict the expressed intent of Congress, DHHS has failed in its nondiscretionary duty to adopt a regulation that effectuates the will of Congress.[7]

[7] The relevant language in both the BBA and BIPA is unambiguous and expresses the clear intent of Congress that the new fee schedules enacted pursuant to both Acts are to apply to services rendered after a date certain. *See,* Balanced Budget Act of 1997, Pub.L. No. 105-33, § 4531, 111 Stat. 451 (1997) (codified in part at § 42 U.S.C 1395m(1)) ("The amendments made by this subsection [providing for the promulgation of a new fee schedule for ambulance services] *shall apply* to services furnished on or after January 1, 2000.") (emphasis added); Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, Pub.L. No. 106-554, § 423, 114 Stat. 2763 (codified in part at 42 U.S.C. § 1395m(1)(2)(E) (2000)) ("The amendment made [to the provisions for paying for certain ambulance mileage] *shall apply* to services furnished on or after July 1, 2001.") (emphasis added).

2. Exhaustion of Other Avenues of Relief

Having found that Defendants violated a nondiscretionary duty, the Court must next evaluate whether Plaintiffs have exhausted all other avenues of relief. Defendants contend that Plaintiffs must submit their claims to DHHS and pursue any appeal administratively prior to invoking the mandamus jurisdiction of this Court. Although Defendants correctly point out that exhaustion of other available avenues of relief is a precondition for seeking mandamus relief, the question is not simply whether Plaintiffs have completed the administrative process. The question is whether "there is another means to obtain adequate review." *In re Bethesda Mem'l Hosp., Inc.*, 123 F.3d 1407, 1408 (11th Cir. 1997). The Court must determine whether the administrative process to which the Government insists Plaintiffs and putative class members must resort is realistically available to Plaintiffs. When "bureaucratic red tape strangles a provider's right to judicial review, the Court may invoke its federal question jurisdiction and mandamus power." *Mem'l Hosp. v. Sullivan*, 779 F. Supp. 1410, 1412 (D.D.C. 1991).

The Court finds that the relief sought by the Plaintiffs in this case could not be secured in the administrative process. Plaintiffs seek the implementation of fee schedules complying with the clear intent of Congress. Achieving this result will require either amending the current fee schedule so that it will apply to the time periods directed by Congress, or adopting a new fee schedule that applies to the relevant time frame and that complies with all the conditions set out by Congress in the BBA and BIPA. It is doubtful that an administrative law judge has the authority to order DHHS to rewrite its regulations to conform to

the direction of Congress. Thus, Plaintiffs are seeking relief that could not be obtained administratively.

The Court also finds that even if an administrative law judge had the authority to grant the type relief requested by Plaintiffs in this case, such relief would not be available under the unique circumstances of this case. Every underlying claim potentially impacted by an order directing DHHS to adopt and apply a lawful fee schedule has already been submitted, considered, approved, and paid under the previous "reasonable charge" methodology. Requiring suppliers who suspected that they may have benefitted from a "national fee schedule" not yet adopted to file an administrative challenge to preserve their legal rights ignores reality.

Prior to February 27, 2002, suppliers like Plaintiffs were in what Defendants' counsel described at oral argument as a "twilight zone" regarding the availability of administrative relief. On one hand, Plaintiffs and the other putative class members were aware that the BBA and BIPA provided for fee schedules applying to services provided after January 1, 2000, and July 1, 2001, respectively. On the other hand, they had no fee schedule on which to base any claim that they might dispute before DHHS or an administrative law judge. It was not until February 27, 2002, that the Government revealed the content of the fee schedule and its intention to apply the new fee schedule only to services furnished on or after April 1, 2002. *See* 67 Fed.Reg. at 9,100.

Prior to February 27, 2002, it would have made no sense for members of the prospective class to do what the Government now says they should have done. The Government recognizes as much: "Until the final rule was in

effect, the ambulance providers and suppliers and providers [*sic*] simply had no expectation of what the ambulance fee schedule would provide as payment . . . ." (Defs.' Mem. Opp'n Pls.' Mot. Summ. J. at 13). Nothing could have been achieved by filing an administrative claim challenging the amounts paid for every service rendered based on the argument that a fee schedule that did not exist would pay them more than the Government had paid. An administrative law judge would have been baffled by such a request. He or she would have had no idea what amount was due, *even if the administrative law judge could have* ruled that the supplier was correct about the legal issue upon which their arguments are based.

The Court also notes that the Government's conduct since adopting the regulation has reinforced the futility of requiring suppliers to resort to the administrative process. Specifically, DHHS, through a program memorandum, has directed its carriers not to accept resubmitted claims for services furnished prior to April 1, 2002. *See* DHHS Program Memorandum Intermediaries/Carriers, *at* http://www.cms.hhs.gov/manuals/pm_trans/AB02129.pdf (Sept. 27, 2002) ("Claims with a date of service prior to April 1, 2002, may not be resubmitted for processing under the new ambulance fee schedule guidelines."). By ordering the carriers not to accept claims from the relevant time frame for resubmission, DHHS has barred the door to the very process it claims that Plaintiffs should have invoked.

It has been recognized that an agency should not "relegate providers to a dead-end procedure under the Medicare statute, and then argue that the provider loses because the Medicare statute is the exclusive means of redress." *Mem'l Hosp.*, 779 F. Supp. at 1412 (citing *Beverly Hosp. v. Bowen*, 872 F.2d 483, 486-87 (D.C. Cir. 1989)).

Plaintiffs seek to compel Defendants to adopt and apply a legal fee schedule consistent with the mandate of Congress. The administrative process cannot grant this relief. Furthermore, Defendants have no discretion in the performance of the duty to enact regulations consistent with the statute authorizing the regulations. Any entitlement to additional reimbursement amounts caused by the application of a fee schedule to services furnished in the relevant time frame would flow directly from an order compelling Defendants to follow the law.

The Court refuses to penalize Plaintiffs for failing to invoke an administrative process that (1) is forever incapable of providing the relief they seek, (2) was effectively unavailable to Plaintiffs prior to the announcement of the fee schedule, and (3) is now unavailable to Plaintiffs because of the actions of Defendants in ordering carriers not to accept resubmitted claims for services furnished in the relevant time frame. Accordingly, the Court finds that Plaintiffs have exhausted all other avenues of available relief for purposes of invoking the Court's mandamus jurisdiction.

3. Defendants' Excuses for Failing to Follow the Law

With the audacity of someone possessing the mistaken belief that they occupy a position of unchecked power, Defendants implicitly argue that they are above the law. Essentially, Defendants complain that their own failure to follow the law regarding the fee schedule implementation dates will cause them future difficulties if they are forced at this time to follow the law. The Court rejects Defendants' excuses for the reasons set forth below.

a. "Budget Neutrality"

Defendants first seek to be rescued by the so-called "budget neutrality" provision of the BBA. That provision states in relevant part:

> In establishing such fee schedule, the Secretary shall
>
> (A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 [2001, 2002] does not exceed the aggregate amount of payments which would have been made for such services [under the reasonable charge methodology adjusted for inflation].

42 U.S.C. § 1395m(1)(3).

Defendants contend that if they are now required to implement a fee schedule retroactively to cover services previously provided and paid for under the "reasonable charge" methodology, they will be unable to do so in a "budget neutral" manner without seeking recoupment from suppliers who were paid more under the "reasonable charge" methodology than they would have been paid had Defendants implemented the new fee schedules as required by Congress.

The Court recognizes that Defendants, due to their own actions, may be required to make payments in excess of what Congress contemplated in order to follow the express provisions in the law regarding the implementation dates of the new fee schedules. However, to apply the "budget neutrality" provision to the exclusion of the clear mandate regarding the effective dates for the fee schedules would likewise produce a result not contemplated by Congress. Therefore, the Court finds as a matter of public

policy and equity that any unexpected consequences (and burdens) caused by Defendants' failure to follow the law should be borne by those who created the lamentable situation and not by innocent intended beneficiaries of the law.[8]

b. Judicial Review

DHHS next contends that the BBA's jurisdictional provision precludes judicial review of the Secretary's refusal to apply a fee schedule to services on or after January 1, 2000. The Court rejects this contention. Although the statute expressly precludes review of fee schedule amounts and their phase-in, it does not preclude review of the one aspect of the BBA at issue in this case – the nondiscretionary effective date of January 1, 2000.[9] The statute provides in relevant part:

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[8] Though the contexts are different, the familiar policy developed through the common law that the wrongdoer should not benefit from his own wrong seems especially apropos to the case at bar. *See, e.g., Bigelow v. RKO Radio Pictures,* 327 U.S. 251, 265, 66 S.Ct. 574, 90 L.Ed. 652 (1946) ("The most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created.").

[9] In considering the limitation of review, Congress chose to limit review of the amounts set by the fee schedule and other discretionary considerations, including the phase-in of payment rates, while leaving open review of other issues. 42 U.S.C. §§ 1395m(1)(2), (5). Congress could have easily precluded all review, but, by not doing so, Congress effectively expressed its intent to allow review of other issues, such as the one presently before the Court. *See Ganem v. Heckler,* 746 F.2d 844, 853 (D.C. Cir. 1984) (fact Congress knows how to withdraw a remedy and has not expressly done so is some indication of congressional intent to preserve that remedy). The BIPA, which governs the application of the fee schedule to claims for in-county mileage, contains no jurisdictional

(Continued on following page)

> There shall be no administrative or judicial review under section 1869 or otherwise *of the amounts established under the fee schedule* for ambulance services under this subsection, including matters described in paragraph (2) [phase-in provisions].

42 U.S.C. § 1395m(1)(5) (emphasis supplied). The Court need not review any "amounts established under the fee schedule" to determine whether Plaintiffs are entitled to the relief they seek. Moreover, the Court's decision in this case is based upon Congress' mandate that certain services provided during a certain time frame shall be paid based upon a new fee schedule. It is unnecessary to review the "phase-in" provisions to reach this conclusion.

The Court recognizes that the statute provides that in establishing the fee schedule, "the Secretary shall . . . (E) phase in the application of the payment rates under the fee schedule in a fair and efficient manner." 42 U.S.C. § 1395m(1)(2)(E). The Secretary's discretion in phasing in application of payment rates, however, cannot eliminate the requirement that there be some payment rates to "phase in" for services furnished on or after January 1, 2000, and for mileage incurred on or after July 1, 2001. The Court finds the BBA's grant of discretion to the Secretary in phasing in the fee schedule is not equivalent to a grant of freedom to legislate a new effective date. As it stands, no fee schedule exists for services furnished from January 1, 2000, through March 31, 2002, as required by the BBA or for qualifying mileage from July 1, 2001, through March 31, 2002, as required by the BIPA. Consequently, there is

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limitation, making the Court's review of that Act's effective date provision equally proper.

nothing to "phase in" during that period. Based on the foregoing, the Court rejects Defendants' contention that the Court does not have the authority to require Defendants to comply with the law and implement fee schedules with the effective dates established by Congress.

c. Defendants' Discretion

The Court also rejects Defendants' contention that Congress gave the Secretary of DHHS discretion to adopt a fee schedule that would "begin as soon after January 1, 2000 as feasible." (*See* Defs.' Mem. Opp'n Pls.' Mot. Summ. J. at 19). The language of the BBA and the BIPA indicate that Congress did not give that discretion to the Secretary. Although Congress could have easily used such discretionary language, it chose not to do so. Congress instead opted to impose a clear mandate that the fee schedules enacted pursuant to the two Acts apply to services rendered on or after the effective dates set forth therein.

Although the BBA is silent on when the regulation must be promulgated, its message is clear in connection with the services to which a fee schedule must be applied. Balanced Budget Act of 1997, § 4531 ("shall apply to services furnished on or after January 1, 2000"). Similarly, the BIPA is silent on when regulations must be promulgated, but it also plainly specifies the services to which its changes must be applied. Medicaid, Medicare and SCHIP Benefits Improvement and Protection Act of 2000, § 423(b)(2) ("shall apply to services furnished on or after July 1, 2001"). The Secretary's position that the fee schedule was to "begin as soon after January 1, 2000 as feasible"

ignores the clear language chosen by Congress.[10] This Court refuses to rewrite the law, a job better suited for the legislative branch than the judiciary.

d. Burdens, Ratification, and Reliance

Finally, the Court rejects Defendants' contentions that they should be allowed to ignore the law because (1) of the alleged burden of compliance, (2) Congress has not stepped in and remedied the noncompliance, and (3) ambulance suppliers allegedly have not detrimentally relied upon the belief that the agency would follow the law. Any additional burdens facing Defendants are creatures of their own making. They should not be allowed to ignore the law because their failure to follow it previously will create a burden if they are required to follow it presently.[11] Furthermore, the Court finds no evidence that Congress has ratified Defendants' failure to comply with the law. The Court likewise finds no evidence or legal authority to support Defendants' contention that its failure to follow the law should be excused because Plaintiffs have not detrimentally relied upon Defendants' obligation to follow the law.

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[10] In contrast to the clear statutory language at issue in this case, the cases relied upon by the government feature statutory language that is truly ambiguous and subject to interpretation. *See Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 409-10, 113 S.Ct. 2151, 124 L.Ed.2d 368 (1993) ("adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive"); *Sullivan v. Everhart*, 494 U.S. 83, 84-85, 110 S.Ct. 960, 108 L.Ed.2d 72 (1990) ("more or less than the correct amount").

[11] *See supra* note 8.

4. Conclusion

As set forth hereinabove, the Court finds that Defendants had a nondiscretionary duty under the BBA to implement a fee schedule for payment of services furnished by ambulance service suppliers after January 1, 2000, and that Defendants breached this duty by failing to implement a fee schedule for services furnished from January 1, 2000, through March 31, 2002. The Court also finds that Defendants had a nondiscretionary duty under the BIPA to implement a system for the payment of in-county mileage in certain states, including North Carolina and Tennessee, starting on July 1, 2001. The Court further finds that Defendants breached this duty by failing to implement such a payment system for qualifying mileage during the period July 1, 2001, through March 31, 2002. Finally, the Court finds that Plaintiffs had no other available avenues for relief, and that mandamus is therefore appropriate in this case. Accordingly, Plaintiffs' Motion for Summary Judgment is granted and Defendants' Motion for Summary Judgment is denied.

The Court hereby orders DHHS to adopt fee schedules within 90 days of the entry of this Order that apply to services furnished during the relevant time period as specified by the Balanced Budget Act of 1997 and the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000. In adopting and applying these fee schedules, DHHS should take into consideration the factors set forth in the BBA and BIPA. However, as previously discussed, budget neutrality should not be considered to the extent that it denies Plaintiffs meaningful relief.

C. Plaintiffs' Motion for Class Certification

Plaintiffs seek certification of a class pursuant to Fed.R.Civ.P. 23(b)(2) for their declaratory and mandamus relief claims.[12] The Court finds that Plaintiffs satisfy the requirements of Rule 23(a) and (b)(2) and that certification is proper as to Plaintiffs' declaratory and mandamus relief claims for the reasons discussed below.[13] Accordingly, Plaintiffs' Motion for Class Certification is granted.

"A class action may be maintained only when it satisfies all the requirements of Fed.R.Civ.P. 23(a) and at least one of the alternative requirements of Rule 23(b)." *Rutstein v. Avis Rent-A-Car Systems, Inc.*, 211 F.3d 1228, 1233 (11th Cir. 2000) (quoting *Jackson v. Motel 6 Multipurpose, Inc.*, 130 F.3d 999, 1005 (11th Cir. 1997)). In determining whether to certify a class, a court generally should not inquire into the merits of the plaintiffs' claims. *See, e.g., Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 157-58, 94 S.Ct. 2140, 40 L.Ed.2d 732 (1974). However, "the class determination [does] generally involve considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action." *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 469, 98 S.Ct. 2454, 57 L.Ed.2d 351 (1978).

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[12] Plaintiffs have invoked this Court's mandamus jurisdiction, under 28 U.S.C. § 1361, whereby a government official may be compelled to follow the law.

[13] In consideration of *Murray v. Auslander*, 244 F.3d 807 (11th Cir. 2001), and other authorities concerning the potential monetary aspect of the injunctive relief sought in the Complaint, the Court reserves the question of whether additional certification under Rule 23(b)(3) is necessary or appropriate until after adjudication of Plaintiffs' equitable claims and implementation of the Court's Order in this case.

Plaintiffs seek to certify the following class:

> All ambulance service suppliers in the United States that provided ambulance services to Medicare eligible recipients and that were entitled to compensation for such services under a fee schedule for suppliers of ambulance services as required by the BBA of 1997.

Plaintiffs contend that for their claims under the BIPA, a subclass should be certified since anyone having a claim under the BIPA would be a member of the class asserting claims under the BBA. Given that the relief granted by the BIPA is available only to certain suppliers in certain states, there will be members of the BBA class that will not have claims under the BIPA.

1. Requirements of Rule 23(a)

Rule 23(a) establishes four prerequisites for certification:

> (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed.R.Civ.P. 23(a). These requirements are commonly referred to as numerosity, commonality, typicality, and adequacy of representation, respectively. *See Amchem Prods., Inc. v. Windsor,* 521 U.S. 591, 613, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997).

a. Numerosity

Rule 23(a)(1) requires that a class be so numerous that joinder of all members is impracticable. Precise enumeration of class members is not necessary for the suit to proceed as a class action. *See Evans v. U.S. Pipe & Foundry Co.*, 696 F.2d 925, 930 (11th Cir. 1983). However, Plaintiffs must provide a good faith estimate, showing that the size of the potential class satisfies the numerosity requirement. The Eleventh Circuit, while not adopting strict numerical guidelines in this regard, has implied that a class of more than forty persons could satisfy Rule 23(a)(1). *See Cox v. Am. Cast Iron Pipe Co.*, 784 F.2d 1546, 1553 (11th Cir. 1986).

Plaintiffs estimate that the number of class members is more than a thousand and, possibly, as many as five thousand ambulance service suppliers. This estimate, which is supported by an estimate reported by the Government, establishes the presumption of impracticality of joinder and satisfies the numerosity requirement of Rule 23(a)(1).[14]

b. Commonality

Rule 23(a)(2) requires a finding that there are "questions of law or fact common to the class." Fed.R.Civ.P.

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[14] *See* Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services, 67 Fed.Reg. 9,100, 9,129 (Feb. 27, 2002) (to be codified at 42 C.F.R. pts. 410 & 414). In this regulation, the Government indicates that there are approximately 10,000 suppliers and providers. *Id.* While Plaintiffs represent only suppliers unaffiliated with hospitals, this Court finds that Plaintiffs' estimate that there are several thousand class members is reasonable.

23(a)(2). Class relief is appropriate when the issues involved are common to the class as a whole and when they turn on questions of law applicable in the same manner to each member of the class. *See Califano v. Yamasaki,* 442 U.S. 682, 700-01, 99 S.Ct. 2545, 61 L.Ed.2d 176 (1979). Rule 23(a)(2) "does not require that all the questions of law and fact raised by the dispute be common . . . ." 7A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1763 (2d ed. 1987 & Supp. 2002); *see also Cox,* 784 F.2d at 1557. The Eleventh Circuit has recognized that, where allegations of wrongdoing arise from a common practice or course of conduct in relation to the class members, the class claims will involve common questions of law and fact. *Kennedy v. Tallant,* 710 F.2d 711 (11th Cir. 1983); *Sanders v. Robinson Humphrey/ American Express, Inc.,* 634 F. Supp. 1048 (N.D. Ga. 1986), *aff'd in part, rev'd in part, Kirkpatrick v. J.C. Bradford & Co.,* 827 F.2d 718 (11th Cir. 1987).

The common nucleus of operative facts and the common controlling legal issue in this case are clear. According to the Complaint, DHHS has thus far failed to implement uniform fee schedules effective January 1, 2000, and July 1, 2001, despite clear congressional directives to do so under the BBA and BIPA, respectively. Instead, DHHS belatedly implemented a new schedule effective April 1, 2002, which left interim periods extending from the congressionally-imposed effective dates through March 31, 2002, uncovered by the new fee schedule.

Plaintiffs seek a declaratory judgment and mandamus relief interpreting the relevant portions of the BBA and BIPA consistent with the plain language of those acts, which requires DHHS to establish uniform fee schedules complying with the BBA and BIPA and to apply the

resulting schedules to services furnished during the relevant time frame. The relief sought by Plaintiffs at this juncture requires only a single determination of law, interpreting the pertinent language in the BBA and BIPA. Indeed, there are no thorny factual issues before the Court because it is undisputed that DHHS has not adopted a fee schedule for the relevant time frames and that payments for services furnished during that period were based on the previous "reasonable charge" methodology. The issue in this case is appropriate for class determination because individual actions could potentially lead to inconsistent adjudications and duties for DHHS. Because Plaintiffs share a common question of law and common facts with each putative class member, the commonality requirement of Rule 23(a)(2) is met.

c. Typicality

Rule 23(a)(3) requires that "the claims or defenses of the representative parties [be] typical of the claims or defenses of the class." Fed.R.Civ.P. 23(a)(3). There must be some nexus between the class representatives' claims or defenses and the common questions of fact or law which unite the class. *Kornberg v. Carnival Cruise Lines, Inc.*, 741 F.2d 1332, 1337 (11th Cir. 1984). A sufficient nexus is established if the claims or defenses of the class representatives arise from the same event or pattern and are based on the same legal theory as the claims or defenses of the putative class members. *Id.* In this case, the legal theory advanced by Plaintiffs is the same for each and every class member and is equally capable of summary adjudication via declaratory judgment and mandamus relief.

Typicality, much like the element of commonality, is established if the representative plaintiffs' claims arise from the same practice or course of conduct and are based on the same legal theory as those of other class members. *Kornberg,* 741 F.2d at 1332; *Kennedy,* 710 F.2d at 711. To satisfy the typicality requirement, the class representatives' claim need not be identical to those of the class members. *Kornberg,* 741 F.2d at 1337. The typicality requirement "primarily directs the district court to focus on whether named representatives' claims have the same essential characteristics as the claims of the class at large." *Appleyard v. Wallace,* 754 F.2d 955, 958 (11th Cir. 1985). In this case, Plaintiffs' claims are substantially identical to those of the other class members. Specifically, each member of the class allegedly has been subjected to the refusal by DHHS to comply with the BBA's requirement for a congressionally mandated compensation system for ambulance services furnished to Medicare patients on or after January 1, 2000.

Typicality is not destroyed even though some individual characteristics or factual differences may exist between the class representatives and other class members. *Appleyard,* 754 F.2d at 958 ("A strong similarity of legal theories will satisfy the typicality requirement despite substantial factual differences."). The question is whether the same unlawful conduct was directed at the Plaintiffs and the putative class members.

In this case, the same conduct, namely the failure to adopt a uniform fee schedule as mandated by Congress for the period in question, underlies the claims of each and every class member. Because the named Plaintiffs and the members of the class are unified in seeking a single declaratory judgment and injunction applicable to all

ambulance service suppliers and are doing so under the same legal theory, this case clearly satisfies the typicality requirement of Rule 23(a)(3).

d. Adequacy of Representation

Rule 23(a)(4) requires that the named plaintiffs fairly and adequately protect the interests of the members of the class. Adequate representation presents two questions: (1) whether Plaintiffs' counsel are qualified, experienced, and generally able to conduct the proposed litigation; and (2) whether Plaintiffs have interests that are antagonistic to the class. *Griffin v. Carlin,* 755 F.2d 1516, 1533 (11th Cir. 1985).

i. Adequacy of Class Representatives

The three named Plaintiffs are clearly members of the proposed class and present common and typical claims. The class definition advanced by Plaintiffs and the substance of the congressional enactments at issue avoid any element of conflict between the class representatives and members of the putative class.

The Court finds the Government's argument that some class members may be "injured" at a later date because of the prospect of lowered payments attributable to concerns of "budget neutrality" is speculative at best. Additionally, no conflict is created simply because certain potential class members may have benefitted from a system that conflicted with the law. *See Fabricant v. Sears Roebuck,* 202 F.R.D. 310, 315 (S.D. Fla. 2001) (plaintiff does not have to show other class members desire the relief sought). This is especially true when the relief sought is an order directing an agency to follow the law.

The Court finds that all ambulance suppliers that rendered services specified in the class definition are affected parties sharing common class characteristics. Therefore, there is no impermissible conflict between class members, and the named representatives are adequate under Rule 23(a)(4). The Court further finds that Coastal Transport, Inc. and Ambulance Services, Inc., who operate in North Carolina and Tennessee, respectively, are adequate representatives for the subclass asserting claims under the BIPA.

ii. Adequacy of Class Counsel

Adequacy of representation also requires a showing that the action will be vigorously prosecuted. The Eleventh Circuit has adopted the following standard in interpreting Rule 23(a)(4):

> We conclude . . . that . . . where the class is represented by competent and zealous counsel, class certification should not be denied simply because of a perceived lack of subjective interest on the part of the named plaintiffs unless their participation is so minimal that they virtually have abdicated to their attorneys the conduct of the case. To require less would permit attorneys essentially to serve as class representatives; to require more could well prevent the vindication of the legal rights of the absent class members under the guise of protecting those rights.

Kirkpatrick v. J.C. Bradford & Co., 827 F.2d 718, 728 (11th Cir. 1987).

The Court is satisfied after having reviewed Plaintiffs' evidentiary submissions that proposed class counsel have extensive experience and expertise in the successful

prosecution of class action litigation and are more than adequate to represent the interests of the class. The efforts of counsel for Plaintiffs thus far in this case show that they are committed to the vigorous prosecution of this action and possess the skills necessary for such a task. Plaintiffs and their counsel, therefore, are well-suited to litigate this case, and the Court is confident they will fairly and adequately protect the interests of the class, in compliance with the mandate of Rule 23(a)(4).

2. Requirements of Rule 23(b)(2).

Once a plaintiff has shown that the requirements of Rule 23(a) are satisfied, the plaintiff must then show that one of the prongs in Rule 23(b) can likewise be met. In the case at bar, Plaintiffs seek to certify a class under Rule 23(b)(2). Certification is proper under Rule 23(b)(2) when the defendant "has acted or refused to act on grounds generally applicable to the class, thereby making final injunctive or declaratory relief appropriate." Fed.R.Civ.P. 23(b)(2). Such relief must be the predominant remedy requested for the class. *Murray v. Auslander,* 244 F.3d 807, 812 (11th Cir. 2001). Unlike a class certified under Rule 23(b)(3), a judgment rendered in a Rule 23(b)(2) class action is binding on all members of the class; there is no "opt out" alternative. *See Guthrie v. Evans,* 815 F.2d 626, 628 (11th Cir. 1987) (noting opt out remedy in Rule 23(c)(2) does not apply to Rule 23(b)(2) class actions).

Plaintiffs in this case seek declaratory and mandamus relief requiring DHHS to fulfill its legal duty as determined by this Court. Furthermore, each member of the putative class shares a predominant and common trait – being an ambulance service supplier that has rendered

services to Medicare eligible recipients, thereby entitling it to reimbursement under federal law. *See* Balanced Budget Act of 1997 § 4531; Medicaid, Medicare and SCHIP Benefits Improvement and Protection Act of 2000 § 423. Based on the foregoing, the Court therefore finds that Plaintiffs have satisfied the requirements of Rule 23(b)(2).

3. Conclusion

For the reasons set forth above, the Court finds that Plaintiffs have met each of the pertinent requirements of subsection (a) and (b)(2) of Rule 23. Plaintiffs' Motion for Class Certification for their declaratory and mandamus relief claims under Rule 23(b)(2) is hereby granted and the Court certifies the following class:[15]

> All ambulance service suppliers in the United States covered by the provisions of the BBA that provided ambulance services to Medicare eligible recipients during the period January 1, 2000, through March 31, 2002.

The Court further certifies the following subclass for Plaintiffs' claims under BIPA:[16]

> All ambulance service suppliers in the states covered by the provisions of the BIPA that provided ambulance services to Medicare eligible recipients during the period July 1, 2001, through March 31, 2002.

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[15] The Court exercises its discretion to modify the class definition proposed by Plaintiffs.

[16] Rule 23(c)(4)(B) provides that when appropriate "a class may be divided into subclasses." The Court finds a subclass appropriate in this case.

The Court appoints the following counsel as co-lead counsel for the above-described class and subclass:

James E. Butler, Jr., and Butler, Wooten,
Fryhofer, Daughtery & Sullivan, LLP
1500 Second Avenue, P.O. Box 2766
Columbus, GA 31902; and
Jonathan H. Waller and Campbell,
Waller & Poer, LLC,
Suite 450, 2100A SouthBridge Parkway,
Birmingham, AL 35209.

III. SUMMARY

To summarize, the Court denies Defendants' Motion to Dismiss and Motion for Summary Judgment, and the Court grants Plaintiffs' Motion for Summary Judgment and Motion for Class Certification as set forth herein-above.

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 03-11392-DD

LIFESTAR AMBULANCE SERVICE, INC., a Georgia Corporation, individually and on behalf of a class of all entities similarly situated, COASTAL MEDICAL TRANSPORT, INC., a North Carolina Corporation; individually and on behalf of a class of all entities similarly situated, AMBULANCE SERVICES, INC., a Tennessee Corporation; individually and on behalf of a class of all entities similarly situated,

Plaintiffs-Appellees,

versus

UNITED STATES OF AMERICA, DEPARTMENT OF HEALTH AND HUMAN SERVICES, TOMMY THOMPSON, in his official capacity as Secretary/Director of D.H.H.S., HEALTH CARE FINANCING ADMINISTRATION (CENTERS FOR MEDICARE & MEDICAID SERVICES), THOMAS A. SCULLY, in his official capacity as Secretary/Director of H.C.F.A./C.M.S.,

Defendants-Appellants.

On Appeal from the United States District Court
for the Middle District of Georgia

(Filed Jun. 29, 2004)

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC
(Opinion ___, 11th Cir., 19___, ___ F.2d ___).

Before: ANDERSON, BLACK and HILL, Circuit Judges.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.

ENTERED FOR THE COURT:

/s/ James C. Hill
UNITED STATES CIRCUIT JUDGE

28 U.S.C.A. § 1361. Action to compel an officer of the United States to perform his duty

The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff.

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42 U.S.C.A. § 405. Evidence, procedure, and certification for payments

(a) Rules and regulations; procedures

The Commissioner of Social Security shall have full power and authority to make rules and regulations and to establish procedures, not inconsistent with the provisions of this subchapter, which are necessary or appropriate to carry out such provisions, and shall adopt reasonable and proper rules and regulations to regulate and provide for the nature and extent of the proofs and evidence and the method of taking and furnishing the same in order to establish the right to benefits hereunder.

* * *

(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or

has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall, after the case is remanded, and after hearing such additional

evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

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42 U.S.C.A. § 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (*l*) of

section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

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42 U.S.C.A. § 1395m. Special payment rules for particular items and services

* * *

(l) Establishment of fee schedule for ambulance services

(1) In general

The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in Title 5, and in accordance with the requirements of this subsection.

(2) Considerations

In establishing such fee schedule, the Secretary shall –

(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) Savings

In establishing such fee schedule, the Secretary shall –

(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points; and

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services

furnished during the previous year, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points.

(4) Consultation

In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) Limitation on review

There shall be no administrative or judicial review under section 1869 or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

(6) Restraint on billing

The provisions of subparagraphs (A) and (B) of section 1395u(b)(18) of this title shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1395u(b)(18)(C) of this title.

(7) Coding system

The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform

coding system specified by the Secretary that identifies the services furnished.

(8) Services furnished by critical access hospitals

Notwithstanding any other provision of this subsection, the Secretary shall pay the reasonable costs incurred in furnishing ambulance services if such services are furnished –

(A) by a critical access hospital (as defined in section 1395x(mm)(1) of this title), or

(B) by an entity that is owned and operated by a critical access hospital,

but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.

(9) Transitional assistance for rural providers

In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates in a rural area (as defined in section 1395ww(d)(2)(D) of this title) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than 1/2 of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

UNITED STATES PUBLIC LAWS
105th Congress – First Session
Convening January 7, 1997

Additions and Deletions are not identified in this document.

For Legislative History of Act, see LH database or Report for this Public Law in U.S.C.C. & A.N. Legislative History section.

PL 105-33 (HR 2015)
August 5, 1997
BALANCED BUDGET

An Act to provide for reconciliation pursuant to subsections (b)(1) and (c) of section 105 of the concurrent resolution on the budget for fiscal year 1998.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Balanced Budget Act of 1997".

SEC. 2. TABLE OF TITLES.

This Act is organized into titles as follows:

Title I – Food Stamp Provisions

Title II – Housing and Related Provisions

Title III – Communications and Spectrum Allocation Provisions

Title IV – Medicare, Medicaid, and Children's Health Provisions

Title V – Welfare and Related Provisions

Title VI – Education and Related Provisions

Title VII – Civil Service Retirement and Related Provisions

Title VIII – Veterans and Related Provisions

Title IX – Asset Sales, User Fees, and Miscellaneous Provisions

Title X – Budget Enforcement and Process Provisions

Title XI – District of Columbia Revitalization

* * *

CHAPTER 3 – AMBULANCE SERVICES

SEC. 4531. PAYMENTS FOR AMBULANCE SERVICES.

(a) INTERIM REDUCTIONS. –

<< 42 USCA § 1395x >>

(1) PAYMENTS DETERMINED ON REASONABLE COST BASIS. – Section 1861(v)(1) (42 U.S.C. 1395x(v)(1)), as amended by section 4451, is amended by adding at the end the following new subparagraph:

"(U) In determining the reasonable cost of ambulance services (as described in subsection (s)(7)) provided during fiscal year 1998, during fiscal year 1999, and during so much of fiscal year 2000 as precedes January 1, 2000, the Secretary shall not recognize the costs per trip in excess of costs recognized as reasonable for ambulance services provided on a per trip basis during the previous fiscal year (after application of this subparagraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending

with the midpoint of the fiscal year involved reduced by 1.0 percentage point. For ambulance services provided after June 30, 1998, the Secretary may provide that claims for such services must include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.".

<< 42 USCA § 1395u >>

(2) PAYMENTS DETERMINED ON REASONABLE CHARGE BASIS. – Section 1842(b) (42 U.S.C. 1395u(b)) is amended by adding at the end the following new paragraph:

"(19) For purposes of section 1833(a)(1), the reasonable charge for ambulance services (as described in section 1861(s)(7)) provided during calendar year 1998 and calendar year 1999 may not exceed the reasonable charge for such services provided during the previous calendar year (after application of this paragraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved reduced by 1.0 percentage point.".

(b) ESTABLISHMENT OF PROSPECTIVE FEE SCHEDULE. –

<< 42 USCA § 1395l >>

(1) PAYMENT IN ACCORDANCE WITH FEE SCHEDULE. – Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)), as amended by section 4315(b), is amended –

(A) by striking "and (Q)" and inserting "(Q)"; and

(B) by striking the semicolon at the end and inserting the following: ", and (R) with respect to ambulance service, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l);".

<< 42 USCA § 1395m >>

(2) ESTABLISHMENT OF SCHEDULE. – Section 1834 (42 U.S.C. 1395m), as amended by section 4541, is amended by adding at the end the following new subsection:

"(l) ESTABLISHMENT OF FEE SCHEDULE FOR AMBULANCE SERVICES. –

"(1) IN GENERAL. – The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in title 5, United States Code, and in accordance with the requirements of this subsection.

"(2) CONSIDERATIONS. – In establishing such fee schedule, the Secretary shall –

"(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

"(B) establish definitions for ambulance services which link payments to the type of services provided;

"(C) consider appropriate regional and operational differences;

"(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

"(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner.

"(3) SAVINGS. – In establishing such fee schedule, the Secretary shall –

"(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2001 and 2002 by 1.0 percentage points; and

"(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2001 and 2002 by 1.0 percentage points.

(4) CONSULTATION. – In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing

individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

"(5) LIMITATION ON REVIEW. – There shall be no administrative or judicial review under section 1869 or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

"(6) RESTRAINT ON BILLING. – The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

"(7) CODING SYSTEM. – The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.".

<< 42 USCA §§ 1395l NOTE, 1395m nt >>

(3) EFFECTIVE DATE. – The amendments made by this subsection shall apply to services furnished on or after January 1, 2000.

UNITED STATES PUBLIC LAWS
106th Congress – Second Session
Convening January 24, 2000

Additions and Deletions are not
identified in this database.
Vetoed provisions within tabular
material are not displayed

PL 106-554 (HR 4577)
December 21, 2000
CONSOLIDATED APPROPRIATIONS – FY 2001

An Act Making consolidated appropriations for the fiscal year ending September 30, 2001, and for other purposes.

Be it enacted by the Senate and House of
Representatives of the United States
of America in Congress assembled,

SECTION 1. (a) The provisions of the following bills of the 106th Congress are hereby enacted into law:

(1) H.R. 5656, as introduced on December 14, 2000.

(2) H.R. 5657, as introduced on December 14, 2000.

(3) H.R. 5658, as introduced on December 14, 2000.

(4) H.R. 5666, as introduced on December 15, 2000, except that the text of H.R. 5666, as so enacted, shall not include section 123 (relating to the enactment of H.R. 4904).

(5) H.R. 5660, as introduced on December 14, 2000.

(6) H.R. 5661, as introduced on December 14, 2000.

(7) H.R. 5662, as introduced on December 14, 2000.

(8) H.R. 5663, as introduced on December 14, 2000.

(9) H.R. 5667, as introduced on December 15, 2000.

<< 1 USCA § 112 NOTE >>

(b) In publishing this Act in slip form and in the United States Statutes at Large pursuant to section 112 of title 1, United States Code, the Archivist of the United States shall include after the date of approval at the end appendixes setting forth the texts of the bills referred to in subsection (a) of this section and the text of any other bill enacted into law by reference by reason of the enactment of this Act.

SEC. 2. (a) Notwithstanding Rule 3 of the Budget Scorekeeping Guidelines set forth in the joint explanatory statement of the committee of conference accompanying Conference Report 105-217, legislation enacted in section 505 of the Department of Transportation and Related Agencies Appropriations Act, 2001, section 312 of the Legislative Branch Appropriations Act, 2001, titles X and XI of H.R. 5548 (106th Congress) as enacted by H.R. 4942 (106th Congress), division B of H.R. 5666 (106th Congress) as enacted by this Act, and sections 1(a)(5) through 1(a)(9) of this Act that would have been estimated by the Office of Management and Budget as changing direct spending or receipts under section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985 were it included in an Act other than an appropriations Act shall be treated as direct spending or receipts legislation, as appropriate, under section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985.

(b) In preparing the final sequestration report required by section 254(f)(3) of the Balanced Budget and

Emergency Deficit Control Act of 1985 for fiscal year 2001, in addition to the information required by that section, the Director of the Office of Management and Budget shall change any balance of direct spending and receipts legislation for fiscal year 2001 under section 252 of that Act to zero.

(c) This Act may be cited as the "Consolidated Appropriations Act, 2001".

Approved December 21, 2000.

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APPENDIX A – H.R. 5656

APPENDIX B – H.R. 5657

APPENDIX C – H.R. 5658

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APPENDIX D-1 – S. 2273

APPENDIX D-2 – S. 2885

APPENDIX E – H.R. 5660

APPENDIX F – H.R. 5661

APPENDIX G – H.R. 5662

APPENDIX H – H.R. 5663

APPENDIX I – H.R. 5667

APPENDIX A – H.R. 5656

That the following sums are appropriated, out of any money in the Treasury not otherwise appropriated, for the Departments of Labor, Health and Human Services, and

Education, and related agencies for the fiscal year ending September 30, 2001, and for other purposes, namely:

* * *

SEC. 423. PAYMENT FOR AMBULANCE SERVICES.

(a) RESTORATION OF FULL CPI INCREASE FOR 2001. –

<< 42 USCA § 1395m >>

(1) IN GENERAL. – Section 1834(l)(3) (42 U.S.C. 1395m(l)(3)) is amended by striking "reduced in the case of 2001 and 2002" each place it appears and inserting "reduced in the case of 2002".

<< 42 USCA § 1395m NOTE >>

(2) SPECIAL RULE FOR PAYMENT FOR 2001. – Notwithstanding the amendment made by paragraph (1), for purposes of making payments for ambulance services under part B of title XVIII of the Social Security Act, for services furnished during 2001, the "percentage increase in the consumer price index" specified in section 1834(l)(3)(B) of such Act (42 U.S.C. 1395m(l)(3)(B)) –

(A) for services furnished on or after January 1, 2001, and before July 1, 2001, shall be the percentage increase for 2001 as determined under the provisions of law in effect on the day before the date of the enactment of this Act; and

(B) for services furnished on or after July 1, 2001, and before January 1, 2002, shall be equal to 4.7 percent.

(b) MILEAGE PAYMENTS. –

<< 42 USCA § 1395m >>

(1) IN GENERAL. – Section 1834(l)(2)(E) (42 U.S.C. 1395m(l)(2)(E)) is amended by inserting before the period at the end the following: ", except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported".

<< 42 USCA § 1395m NOTE >>

(2) EFFECTIVE DATE. – The amendment made by paragraph (1) shall apply to services furnished on or after July 1, 2001.

67 FR 9100

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410 and 414

[HCFA-1002-FC]

RIN 0938-AK30

Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Non-emergency Ambulance Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule establishes a fee schedule for the payment of ambulance services under the Medicare program, implementing section 1834(l) of the Social Security Act. As required by that section, the proposed rule on which this final fee schedule for ambulance services is based was the product of a negotiated rulemaking process that was carried out consistent with the Federal Advisory Committee Act and the Negotiated Rulemaking Act of 1990. The fee schedule described in this final rule will replace the current retrospective reasonable cost payment system for providers and the reasonable charge system for suppliers of ambulance services. In addition, this final rule requires that ambulance suppliers accept Medicare assignment; codifies the establishment of new Health Care Common Procedure Coding System (HCPCS) codes to be reported on claims for ambulance services; establishes increased payment under the fee schedule for ambulance

services furnished in rural areas based on the location of the beneficiary at the time the beneficiary is placed on board the ambulance; and revises the certification requirements for coverage of nonemergency ambulance services.

DATES: Effective date: April 1, 2002.

Comment date: We will consider comments on portions of the regulation with respect to the following sections of the Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act (BIPA), Pub. L. 106-554: the provisions implementing the portion of section 205 relating to cost reimbursement for ambulance services furnished by certain critical access hospitals (CAHs) (§ 414.601 and § 414.610(a)); the provisions implementing section 221, establishing the rate for rural ambulance mileage greater than 17 miles and up to 50 miles (§ 414.610(c)(5)); the provisions implementing section 423 with regard to immediate payment of the full ambulance services fee schedule amount for in-county ground mileage under certain circumstances (§ 414.615(g)), if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 29, 2002.

ADDRESSES: Mail written comments (an original and 3 copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1002-FC, PO Box 8013, Baltimore, MD 21244-8013.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or, Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-8013.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS-1002-FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room C5-12-08 at 7500 Security Blvd, Baltimore, MD, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. Please call (410) 786-7197 to view these comments.

For information on ordering copies of the **Federal Register** containing this document and electronic access, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Glenn McGuirk, (410) 786-5723.

SUPPLEMENTARY INFORMATION: *Copies:* To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by

calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is $9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register.**

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I. Background

The Medicare program pays for transportation services for Medicare beneficiaries when other means of transportation are contraindicated. Ambulance services are divided into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport. These services include the levels of service listed below, which we define later in this rule.

For Ground:

- Basic Life Support (BLS)
- Advanced Life Support, Level 1 (ALS1)
- Advanced Life Support, Level 2 (ALS2)
- Specialty Care Transport (SCT)
- Paramedic ALS Intercept (PI)

For Air:

- Fixed Wing Air Ambulance (FW)
- Rotary Wing Air Ambulance (RW)

Currently payment levels for ambulance services depend, in part, upon the entity that furnishes the services. Providers (hospitals, including critical access hospitals, skilled nursing facilities, and home health agencies) are paid on a retrospective reasonable cost basis. Suppliers, which are entities that are independent of any provider, are paid on a reasonable charge basis. This final rule establishes a fee schedule payment system for all such services.

A. *History of Medicare Ambulance Services*

1. Original Statutory Coverage of Ambulance Services

Under section 1861(s)(7) of the Social Security Act (the Act), Medicare part B (Supplementary Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated. The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that (1) the ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition, and (2) only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and S. Rep. No. 404, 89th Cong., 1st Sess., Pt I, 43 (1965)). The

reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

2. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are located at 42 CFR part 410, subpart B. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare part B. Ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at § 410.40.

On January 25, 1999, we published a final rule with comment period (64 FR 3637) to revise and update Medicare policy concerning ambulance services. It identified destinations to which ambulance services are covered, established requirements for the vehicles and staff used to furnish ambulance services, and clarified coverage of nonemergency ambulance services for Medicare beneficiaries. This rule also implemented section 4531(c) of the Balanced Budget Act of 1997 (BBA), Pub. L. 105-33, concerning Medicare coverage for paramedic intercept services in rural communities.

We published a final rule on March 15, 2000 (65 FR 13911) responding to public comments received on the January 25, 1999 final rule with comment period regarding Medicare coverage of, and payment for, paramedic intercept ambulance services in rural communities. It also implemented section 412 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Pub. L. 106-113, by adding a new definition of a rural area.

3. Negotiated Rulemaking Process

Section 1834(l)(1) of the Act provides that the ambulance fee schedule be established through the negotiated rulemaking process described in the Negotiated Rulemaking Act of 1990 (Pub. L. 101-648, 5 U.S.C. 581-590). Negotiations were conducted by a committee chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). The Negotiated Rulemaking Committee on the Medicare Ambulance Services Fee Schedule (the Committee) consisted of individuals associated with national organizations that represent interests that are likely to be significantly affected by the fee schedule. There was a public solicitation through the **Federal Register** on January 22, 1999 (64 FR 3474) for participation in the negotiated rulemaking process. (Additional information about the negotiations can be found in the January 22, 1999 **Federal Register** notice or may be accessed at our Internet Web site at *http://www.hcfa.gov/medicare/ambmain.htm.*)

The Committee discussed various issues related to the ambulance fee schedule and a consensus Committee Statement was signed on February 14, 2000.

4. Proposed Rule

In our proposed rule, we discussed the negotiated rulemaking procedure used to formulate our policy for the ambulance fee schedule and proposed additions to part 414 based on recommendations of the Committee. We discussed operational and regional variations, cost of living differences, services furnished in rural areas, and mileage. The structure of the fee schedule, the ambulance

inflation factor, and phase-in methodology were also discussed.

In addition, we proposed changes unrelated to the Committee's consensus statement on matters including coverage of ambulance services, physician certification requirements, payment during the first year, and billing method. We discussed local or State law related to ambulance services, mandatory assignment, and miscellaneous payment policies, including multiple patients, pronouncement of death, multiple arrivals, and BLS services furnished in an ALS vehicle.

We presented our methodology for determining the conversion factor (CF) and for implementing the fee schedule. We discussed expenditure control for ambulance services and adjustments to account for inflation. Finally, to seek input on the desirability and flexibility of developing a code set to describe patients' conditions, we included an addendum containing a list of medical conditions.

In accordance with the negotiated rulemaking procedures, we proposed the following additions to part 414 based on the recommendations of the Committee.

1. Definitions and levels of services. In part 414, we proposed to add subpart H, § 414.605 to define several levels of ground ambulance services ranging from BLS to specialty care transport. (Note that the term "ground" refers to both land and water transportation. The definitions and RVUs for each of the levels of service were described in § 414.605, "Definitions.") Also, we proposed that the rate per ground mile for all ground ambulance services would be the same for each level of service.

We stated in the proposed rule that there would be two levels of air ambulance services to distinguish fixed wing from rotary wing (helicopter) aircraft. In addition, to recognize the operational cost differences of the two types of aircraft, there would be two distinct payment amounts for air ambulance mileage. The air ambulance services mileage rate would be calculated per actual loaded (patient onboard) miles flown, expressed in statute miles (that is, ground, not nautical, miles.)

The Committee used an industry consensus document, described below, as the basis for defining the levels of ambulance service.

During 1990, the development of a training blueprint and the evaluation of current levels of training and certification for prehospital providers were identified as priority needs for national emergency medical services (EMS). As a result, the National EMS Training Blueprint Project was formed.

In May 1993, representatives of EMS organizations adopted the National EMS Education and Practice Blueprint consensus document (Blueprint). As stated in the National EMS Education and Practice Blueprint, Executive Summary, printed September 1993, "The Blueprint divides the major areas of prehospital instruction and/or core performance into 16 'core elements.'" For each core element, the Blueprint recommends that there be four levels of prehospital EMS providers "corresponding to various knowledge and skills in each of the core elements." At the "First Responder" level, personnel use a limited amount of equipment to perform initial assessments and interventions. The "EMT-Basic" has the knowledge and skill of the First Responder, but is also qualified to function as the

minimum staff for an ambulance. "EMT-Intermediate" personnel has the knowledge and skills identified at the First Responder and EMT-Basic levels, but is also qualified to perform essential advanced techniques and to administer a limited number of medications. The "EMT-Paramedic," in addition to having the competencies of an EMT-Intermediate, has enhanced skills and can administer additional interventions and medications.

Since the release of the Blueprint, a consensus panel of EMS educators has recommended that the Department of Transportation, National Highway Traffic and Safety Administration (DOT/NHTSA) revise the document. DOT/NHTSA has accepted the recommendation of the panel and expects to release a revised Blueprint or an equivalent document in the near future.

To request a copy of the National Emergency Medical Services Education and Practice Blueprint, please fax your request to: NHTSA/EMS Division, (202) 366-7721. Please include your name and address. Because of staffing and resource limitations NHTSA will forward the requested document via regular mail.

We proposed the following seven levels of ambulance services.

a. Basic Life Support (BLS) – When medically necessary, the provision of basic life support (BLS) services as defined in the National Emergency Medical Services EMS Education and Practice Blueprint for the Emergency Medical Technician-Basic (EMT-Basic) including the establishment of a peripheral intravenous (IV) line.

b. Advanced Life Support, Level 1 (ALS1) – When medically necessary, this is the provision of an assessment

by an advanced life support (ALS) ambulance provider or supplier or the furnishing of one or more ALS interventions. An ALS assessment is performed by an ALS crew and results in the determination that the beneficiary's condition requires an ALS level of care, even if no other ALS intervention is performed. An ALS provider or supplier is defined as a provider or supplier whose staff includes an individual trained to the level of the EMT-Intermediate or Paramedic as defined in the National EMS Education and Practice Blueprint. An ALS intervention is defined as a procedure beyond the scope of an EMT-Basic as defined in the National EMS Education and Practice Blueprint. These definitions are discussed later in the "Discussion of Public Comments on the Proposed Rule" section.

c. Advanced Life Support, Level 2 (ALS2) – When medically necessary, the administration of at least three different medications or the provision of one or more of the following ALS procedures:

- Manual defibrillation/cardioversion.
- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.
- Chest decompression.
- Surgical airway.
- Intraosseous line.

d. Specialty Care Transport (SCT) – When medically necessary, for a critically injured or ill beneficiary, a level of interhospital service furnished beyond the scope of the paramedic as defined in the National EMS Education and

Practice Blueprint. This is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area (for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training).

e. Paramedic ALS Intercept (PI) – These services are defined in § 410.40(c) "Paramedic ALS Intercept Services". These are ALS services furnished by an entity that does not provide the ambulance transport. Under limited circumstances, Medicare payment may be made for these services. (To obtain additional information about paramedic ALS intercept services, please refer to the March 15, 2000 final rule (65 FR 13911).)

f. Fixed Wing Air Ambulance (FW) – We proposed that fixed wing air ambulance services would be covered when the point from which the beneficiary is transported to the nearest hospital with appropriate facilities is inaccessible by land vehicle, or great distances or other obstacles (for example, heavy traffic) and the beneficiary's medical condition is not appropriate for transport by either BLS or ALS ground ambulance.

g. Rotary Wing Air Ambulance (RW) – We proposed that rotary wing (helicopter) air ambulance services are covered when the point from which the beneficiary is transported to the nearest hospital with appropriate facilities is inaccessible by ground vehicle, or great distances or other obstacles (for example, heavy traffic) and the beneficiary's medical condition is not appropriate for transport by either BLS or ALS ground ambulance.

B. Current Payment System

The Medicare program pays for ambulance services on a reasonable cost basis when furnished by a provider and on a reasonable charge basis when furnished by a supplier. (For purposes of this discussion, the term "provider" means all Medicare-participating institutional providers that submit claims for Medicare ambulance services (hospitals, including critical access hospitals (CAHs); skilled nursing facilities (SNFs); and home health agencies (HHAs).) The term "supplier" means an entity that is other than a provider. See § 400.202.) The reasonable charge methodology bases payment for ambulance services furnished by ambulance suppliers on the lowest of the customary, prevailing, actual, or inflation indexed charge (IIC).

The following describes the current reasonable charge billing methods for ambulance services:

- Method 1: A single, all-inclusive charge reflecting all services, supplies, and mileage.
- Method 2: One charge reflecting all services and supplies (base rate) with a separate charge for mileage.
- Method 3: One charge for all services and mileage, with a separate charge for supplies.
- Method 4: Separate charges for services, mileage, and supplies.

C. Organization of the Preamble

The headings for the discussion of various policy issues in this final rule correspond to the headings used in the September 2000 proposed rule. For the convenience of the reader, the analysis of comments and their responses are integrated with the discussion of each issue.

D. Recent Legislation

We do not intend for the aggregate amount of payments under the ambulance fee schedule to be lower than the aggregate amount of payments under the current system. Consequently, as described below, we will adjust the conversion factor (CF) and air ambulance rates if actual experience under the fee schedule is different from the assumptions used to determine the initial CF and air ambulance rates.

We estimate that total spending (the sum of Medicare program payments and beneficiary copayments) for ambulance services over the next five years will be:

Calendar year	Payments ($ billion)
2002	2.7
2003	2.8
2004	2.9
2005	3.0
2006	3.1

These estimates are based on the assumption that the ambulance inflation factor will be 2.2 percent for 2002 and 2.5 percent for years 2003 through 2006, that the ratio of services furnished at the various levels of intensity (for example, BLS versus ALS1 versus ALS2, etc.) will not change and that there will be an increase in Medicare beneficiary enrollment of 0.9, 0.8, 0.9, 1.3 and 1.0 percent in the years 2002 through 2006, respectively. To the extent that any of these assumptions are different from actual experience, actual payments will be higher or lower than these estimates.

As we indicated in the proposed rule, we will monitor payment data and evaluate whether the assumptions used to establish the original CF (for example, the ratio of the volume of BLS services to ALS services) are accurate. If the actual proportions among the different levels of service are different from the projected amounts, we will adjust the CF accordingly and apply this adjusted CF prospectively. Similarly, if the level of low charge billing is significantly different from the assumed level, we will also adjust the CF and apply such an adjusted CF prospectively.

Over the past 20 years, the Congress has been moving towards fee schedules and prospective payment systems for Medicare payment. In the case of ambulance services, the reasonable charge methodology has resulted in a wide variation of payment rates for the same service. In addition, this payment methodology is administratively burdensome, requiring substantial recordkeeping for historical charge data. The Congress, under the BBA, mandated the establishment of a national fee schedule for payment of ambulance services.

1. Balanced Budget Act of 1997 (BBA)

Section 4531(b)(2) of the BBA added a new section 1834(l) to the Social Security Act (the Act). Section 1834(l) of the Act requires the establishment of a national fee schedule for payment of ambulance services under Medicare part B through negotiated rulemaking. This section also requires that in establishing the ambulance fee schedule, we will –

- Establish mechanisms to control increases in expenditures for ambulance services as a benefit under part B of the Medicare program;

- Establish definitions for ambulance services that link payments to the types of services furnished;

- Consider appropriate regional and operational differences;

- Consider adjustments to payment rates to account for inflation and other relevant factors;

- Phase in the fee schedule in an efficient and fair manner; and,

- Require that payment for ambulance services be made only on an assignment-related basis.

In addition, the BBA requires that ambulance services covered under Medicare be paid based on the lower of the actual billed charge or the ambulance fee schedule amount. The law also provides, in a paragraph entitled "Savings," that total payments during the first year of the ambulance fee schedule may be no more than what would have been paid if the ambulance fee schedule were not in effect. In addition, we are implementing the provisions of a regulation proposed in June 1997 that we would have made final prior to the fee schedule, but decided instead to implement coincident with the fee schedule, as discussed below.

Section 4531(c) of BBA 1997 provided for payment of paramedic advanced life support (ALS) intercept services directly to the entity furnishing those services under limited circumstances. Paramedic ALS intercept services are ALS services delivered by paramedics that operate separately from the agency that provides the ambulance transport. This type of service is most often provided for an emergency ambulance transport in which a local volunteer ambulance that can provide only basic life

support (BLS) level service is dispatched to transport a beneficiary. If the beneficiary needs ALS services such as EKG monitoring, chest decompression, or IV therapy, another entity dispatches a paramedic to meet the BLS ambulance at the scene or once the ambulance is on the way to the hospital. The ALS paramedics then provide their services to the beneficiary. One statutory criteria for payment is that the service must be furnished in a rural area. Other criteria (for example, the transporting entity must be volunteer) limited the application of this provision. The program defined a rural area as one that was outside any area defined by the Office of Management and Budget as a Metropolitan Statistical Area, (MSA) or New England County Metropolitan Area (NECMA).

2. Balanced Budget Refinement Act of 1999

Section 412 of the BBRA provided a new definition for the term "rural" in the context of the Medicare coverage provision for paramedic ALS intercept services. The BBRA states that, effective for services furnished on or after January 1, 2000:

"An area shall be treated as a rural area if it is designated as a rural area by any law or regulation of the State or if it is located in a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith modification, originally published in the **Federal Register** on February 27, 1992 (57 FR 6725)."

This definition applies only to the Medicare paramedic ALS intercept benefit implemented at § 410.40(c). This is a very limited benefit and to date we know of only one State (New York) with areas that meet the statutory requirements. (See the March 15, 2000 final rule on "Coverage of,

and Payment for, Paramedic Intercept Ambulance Services" (65 FR 13911).) For all other ambulance services, the definition of "rural" specified in this final rule will apply.

3. The Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA)

BIPA provided the following changes to the ambulance fee schedule that have been incorporated into this rule.

a. Critical Access Hospital (CAH)

The proposed rule would have applied the ambulance fee schedule to all entities furnishing ambulance services to Medicare beneficiaries. Section 205 of BIPA provided that CAHs, or entities owned and operated by them, are paid for ambulance services based on reasonable cost if there is no other ambulance provider or supplier within a 35-mile drive. As a result, these entities are exempt from the ambulance fee schedule described in this final rule. These entities are also exempt from the current cost-per-trip inflation cap applicable to providers. This cap, established by section 4531(a)(1) of the BBA, limits increases in the cost per trip of ambulance services from one year to the next by the consumer price index for all urban consumers, reduced by 1 percentage point. Implementation of section 205 of BIPA requires us to establish a process for a CAH to qualify for this exemption. Such a process was addressed in a separate final rule, "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Rates and Costs of Graduate Medical Education; Fiscal

Year 2002 Rates, Etc.; Final Rules," published August 1, 2001 (66 FR 39828). The payment policy component is addressed in this rule.

Comment: Some commenters believe that we should pay all CAHs based on cost payment for ambulance services because, in their view, section 1834(g) of the Act requires that CAHs be paid on a reasonable cost basis for all services, not just their services to inpatients and outpatients.

Response: The Congress, in section 205 of BIPA, specifically provides that ambulance services furnished on or after December 21, 2000 by a CAH or an entity owned and operated by a CAH be paid on a reasonable cost basis if the CAH or entity is the only provider or supplier located within a 35-mile drive of the CAH or entity. BIPA did not grant CMS broad authority to pay other CAHs on a cost basis. Therefore, CAHs that do not fall within the ambit of section 205 of BIPA will be paid under the ambulance fee schedule.

b. Rural Ambulance Mileage

The proposed rule would have established payment for rural mileage greater than 17 miles at the same rate as mileage within urban areas. Section 221 of BIPA provided that the payment rate for rural ambulance mileage greater than 17 miles and up to 50 miles be increased by not less than one-half of the additional payment per mile established for the first 17 miles of a rural ambulance trip. We are establishing this rate at one-half of the additional payment per mile established for the first 17 miles of a rural ambulance trip. This amount is the minimum that is required by the plain language of the law and is not

discretionary. We believe that proposed rulemaking, which would be necessary to set the amount at a level higher than the minimum, is impracticable in this instance for timely implementation [sic] the law. This is consistent with the amount established by the Congress for the period prior to April 1, 2002. We are waiving proposed rulemaking for this provision and will implement it as a final rule with comment period. Therefore, we will accept public comments on this policy.

c. Inflation Factor

The proposed rule would have increased the per trip payments for services furnished in 2001 over the per trip payments for these services furnished in 2000 by an amount equal to the change in the CPI-U reduced by one percent. Section 423 of BIPA provided that the ambulance inflation factor for services furnished during the period July 1, 2001 through December 31, 2001 be equal to 4.7 percent, an increase of two percentage points over the rate in the proposed rule. We have implemented this provision without proposed rulemaking because it was self-implementing, not discretionary for CMS, and did not require us to interpret the law. For that reason, we find notice and comment rulemaking unnecessary.

d. Ground Ambulance Mileage

The proposed rule would have paid for all ground ambulance mileage during a four-year transition period based on a blend of the current payment rate and the fee schedule rate. Section 423 provided that there will be no phased-in blended payment for mileage for ambulance suppliers paid by carriers in those States in which, prior to

the fee schedule, the carrier's payment to all suppliers did not include separate payment for all in-county ambulance mileage. Mileage paid by these carriers in these States will be paid based on the full fee schedule amount. This provision does not apply to providers. Because the law does not permit CMS to exercise any discretion in implementing the policy, we find notice and comment rulemaking unnecessary. Therefore, we are waiving proposed rulemaking for this provision and will implement it as a final rule with comment. Therefore, we will accept public comments on this policy.

E. Components of Ambulance Fee Schedule Payment Amounts

Ambulances may be ground, water or air. We proposed that the payment amount for each ambulance service paid under the ambulance fee schedule would be the sum of a base payment amount and a mileage rate. The base payment amount for each air ambulance service paid under the ambulance fee schedule would be the product of two primary factors: (1) A nationally uniform unadjusted base rate; and (2) a geographic adjustment factor for an ambulance fee schedule area.

We proposed that the base payment amount for each ground or water ambulance service paid under the ambulance fee schedule would be the product of three factors –

(1) A nationally uniform relative value for the service;

(2) A geographic adjustment factor for an ambulance fee schedule area; and

(3) A nationally uniform conversion factor (CF) for the service.

We are proceeding with these proposals in this final rule. A detailed description of these factors is discussed in this final rule.

Relative value units (RVUs) measure the value of ambulance services relative to the value of a base level ambulance service. Thus, if the value of the resources necessary to furnish service B is twice the value of the resources needed to furnish service A, service B will have twice as many RVUs as service A. RVUs are multiplied by a CF expressed as a dollar value to produce a payment amount. The RVUs represent, on average, the relative resources associated with the various levels of ambulance services. RVUs for each level of service were established by the Committee.

Because the fee schedule is based on the relative values of different levels of ground ambulance services relative to a basic life support ground ambulance service, a factor is needed to convert the relative value to a dollar amount which is the national base payment rate. In order to determine the CF, the general approach is first to determine the total amount of money available and divide that total by the total number of relative value units that we estimate will be in the fee schedule for the base year. As we describe in more detail below, we used 1998 Medicare ambulance claims data to determine the total RVUs in this calculation.

Section 1834(1)(3) of the Act states that, in establishing the ambulance fee schedule, the Secretary must ensure that the aggregate amount of payment made for ambulance services in calendar year (CY) 2000 (originally

expected to be the first year of the fee schedule) does not exceed the aggregate amount of payment that would have been made absent the fee schedule. In the January 22, 1999 notice concerning the meetings of the Committee, we stated that we were postponing final agency action, pending establishment of the ambulance fee schedule, on a proposal to base payment on the level of service (ALS or BLS) actually needed by the beneficiary. We stated our position that the savings that would have been realized through implementation of that policy in 1998 should not be lost to the Medicare program. We estimated that $65 million in program savings would have been realized in 1998 if this policy had been in effect at that time.

Section 4531(b)(3) of the BBA, which added section 1834(l)(3) to the Act, provided that the fee schedule was to be effective for ambulance services furnished on or after January 1, 2000. However, because of other statutory obligations, the scope of systems changes required to implement the ambulance fee schedule, and the need to ensure that our computerized systems were compliant with the Year 2000 (Y2K) requirements, we could not meet this statutory deadline.

In the September 12, 2000 proposed rule, we indicated our intention to implement the fee schedule beginning January 1, 2001. However, although the proposed rule was largely based on an agreement reached as part of a negotiated rulemaking process with representatives of the ambulance industry and other interests, we received over 340 public comments. We did not have sufficient time to carefully consider all comments and publish a final rule in time to implement the fee schedule by January 1, 2001. This final rule establishes an implementation date of April 1, 2002. Our objective is to have the ambulance fee schedule

become effective as soon as we can, in this case, April 1, 2002.

F. Negotiated Rulemaking Process

Section 1834(l)(1) of the Act provided that the ambulance fee schedule be established through the negotiated rulemaking process described in the Negotiated Rulemaking Act of 1990 (Pub. L. 101-648, 5 U.S.C. 581-590). Prior to using negotiated rulemaking under the Negotiated Rulemaking Act, the head of an agency must generally consider whether the following conditions exist:

- There is a need for a rule.

- There are a number of identifiable interests that will be significantly affected by the rule.

- There is a reasonable likelihood that a committee can be convened with a balanced representation of persons who –

  + Can adequately represent the interests identified; and,

  + Are willing to negotiate in good faith to reach a consensus on the proposed rule.

- There is a reasonable likelihood that a committee will reach a consensus on the proposed rule within a fixed timeframe.

- The negotiated rulemaking procedure will not unreasonably delay the notice of proposed rulemaking and the issuance of a final rule.

- The agency has adequate resources and is willing to commit its resources, including technical assistance, to the committee.

- The agency, to the maximum extent possible consistent with the legal obligations of the agency, will use the consensus of the committee as the basis for the rule proposed by the agency for notice and comment.

Negotiations were conducted by a committee chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). We used the services of an impartial convener to help identify interests that would be significantly affected by the proposed rule (including residents of rural areas) and the names of organizations who were willing and qualified to represent those interests. The Negotiated Rulemaking Committee on the Medicare Ambulance Services Fee Schedule (the Committee) consisted of individuals associated with national organizations that represent interests that were likely to be significantly affected by the fee schedule. (Additional information about the negotiations can be found in the January 22, 1999 **Federal Register** notice or may be accessed at our Internet Web site at *http://www.hcfa.gov/medicare/ambmain.htm.*)

To the extent that the proposed rule accurately reflects the Committee Statement, signed on February 14, 2000, each member of the Committee has agreed not to comment on those issues on which consensus was reached.

G. Interaction With the Proposed Rule Published on June 17, 1997

On June 17, 1997, we published a proposed rule (62 FR 32715) in the **Federal Register** to revise and update the Medicare ambulance services regulations at § 410.40. Specifically, we proposed: To base Medicare payment on the level of ambulance service required to treat the beneficiary's condition; to clarify and revise the policy on coverage of nonemergency ambulance services; and to set national vehicle, staff, billing, and reporting requirements. As noted above, section 1834(1)(2) of the Act provides, in part, that in establishing the ambulance fee schedule, the Secretary establish definitions for ambulance services that link payments to the types of services furnished. One of the provisions of the June 17, 1997 proposed rule would have defined ambulance services as either BLS or ALS and linked Medicare payment to the type of service required by the beneficiary's condition. We received a large number of comments on this provision, and, in general, commenters were very concerned about our proposal.

II. Discussion of Public Comments on the Proposed Rule

In response to the publication of the September 2000 proposed rule, we received approximately 340 comments. We received comments from, among others, national ambulance organizations, emergency physician groups and State emergency programs. The majority of the comments addressed issues related to medical condition descriptions lists, physician certification, and definitions of services.

As stated previously, the headings for the policy issues in this final rule correspond to the headings used in the

September 2000 proposed rule. For the convenience of the reader, the analysis of comments and their responses are integrated with the discussion of each issue.

A. Proposals Based on Negotiated Rulemaking

In our proposed rule, published September 12, 2000, we discussed the negotiated rulemaking procedures used to formulate our policy for the ambulance fee schedule.

Comment: One commenter stated that we should reconvene the Committee to consider the comments received in response to the proposed rule and also reconvene the Committee annually to consider all future adjustments.

Response: We have decided not to reconvene the Committee. We have adhered to the Committee's recommendations in all cases in which the Committee addressed an issue. Furthermore, some issues were excluded from the negotiation process, and therefore, were not within the purview of the Committee. Also, we believe that reconvening the Committee would significantly postpone the implementation of the regulation.

Comment: Commenters from various regions stated that their organizations were not represented on the Committee.

Some commenters believe that the North American Association of Public Utility Models (NAPUM) should have been included as a participant in the negotiated rulemaking process. NAPUM could have shared its Public Utility Model EMS system in the development of the ambulance fee schedule.

Another commenter stated that the fixed wing air ambulance organizations were not properly represented at the negotiated rulemaking meetings and, therefore, the payment rates for fixed wing air mileage are inadequate.

Response: There was a public solicitation through the **Federal Register** (January 22, 1999) for participation in the negotiated rulemaking process. All interested parties who responded to this public notice were given due consideration by the neutral convener whom we retained for this purpose. Also, the Association of Air Medical Services (AAMS), which has approximately 130 members that are fixed wing providers, represented the air ambulance industry.

In the proposed rule, we proposed the following additions to part 414 based on the recommendations of the Committee.

1. Definitions and Levels of Services

In part 414, we proposed to add subpart H, § 414.605 that would define several levels of ground ambulance services ranging from BLS to specialty care transport (SCT). (Note that the term "ground" refers to both land and water transportation. The definitions and RVUs for each of the levels of service are described in § 414.605, "Definitions.") Also, this section proposed that the mileage rate paid under the fee schedule per ground mile would be the same for each level of ground ambulance service.

In the course of establishing national standards for ALS and BLS during 1990, the development of a training blueprint and the evaluation of current levels of prehospital provider training and certification were identified by

the national emergency medical services (EMS) industry as a priority need for EMS. As a result, the National EMS Training Blueprint Project was formed.

In May 1993, representatives of EMS organizations adopted the Blueprint consensus document. This consensus document was used as the basis for defining the levels of service. As stated in the Blueprint, Executive Summary, printed September 1993, "The Blueprint divides the major areas of prehospital instruction and/or core performance into 16 'core elements.'" For each core element, the Blueprint recommended that there be four levels of prehospital EMS providers "corresponding to various knowledge and skills in each of the core elements." At the First Responder level, personnel use a limited amount of equipment to perform initial assessments and interventions.

The EMT-Basic has the knowledge and skill of the First Responder, but is also qualified to function as the minimum staff for an ambulance. EMT-Intermediate personnel has the knowledge and skills identified at the First Responder and EMT-Basic levels, but is also qualified to perform essential advanced techniques and to administer a limited number of medications. The EMT-Paramedic, in addition to having the competencies of an EMT-Intermediate, has enhanced skills and can administer additional interventions and medications.

After the release of the Blueprint, a consensus panel of EMS educators had recommended that DOT/NHTSA revise the document. The Department of Transportation, National Highway Traffic and Safety Administration (DOT/NHTSA) has accepted the recommendation of the panel and is expected to release a revised Blueprint or an equivalent document in the near future.

To request a copy of the National Emergency Medical Services Education and Practice Blueprint, please fax your request to: NHTSA/EMS Division, (202) 366-7721. Please include your name and address. Because of staffing and resource limitations, NHTSA will forward the requested document via regular mail.

Levels of Ambulance Services

Payment for all ambulance services under the fee schedule will be based on a base rate payment. In addition, there will be a separate payment for mileage.

In the proposed rule, we stated that there would be two levels of air ambulance services to distinguish fixed wing from rotary wing (helicopter) aircraft. In addition, to recognize the operational cost differences of the two types of aircraft, there would be two distinct payment amounts for air ambulance mileage. The air ambulance services mileage rate would be calculated per actual loaded (patient on board) miles flown, expressed in statute miles (that is, ground, not nautical, miles).

In the proposed rule, we proposed the seven levels of ambulance services shown below. We expressed the qualifications for staff at the various levels in terms of the Blueprint. As just noted, we are revising the proposed qualifications to indicate that the vehicle staffing will comply with existing State and local laws for each level of service.

a. *Basic Life Support (BLS)* – In the proposed rule, we stated that, when medically necessary, the provision of basic life support (BLS) services is defined in the National Emergency Medicine Services (EMS) Education and

Practice Blueprint for the Emergency Medical Technician-Basic (EMT-Basic) including the establishment of a peripheral intravenous (IV) line.

b. *Advanced Life Support, Level 1 (ALS1)* – In the proposed rule, we stated that, when medically necessary, this level of service requires the provision of an assessment by an advanced life support (ALS) ambulance provider or supplier and the furnishing of one or more ALS interventions. An ALS assessment is performed by an ALS crew and results in the determination that the beneficiary's condition requires an ALS level of care, even if no other ALS intervention is performed. The proposed rule also stated that an ALS provider or supplier is defined as a provider trained to the level of the EMT-Intermediate or Paramedic as defined in the National EMS Education and Practice Blueprint. We proposed to define an ALS intervention as a procedure beyond the scope of an EMT-Basic as defined in the National EMS Education and Practice Blueprint.

c. *Advanced Life Support, Level 2 (ALS2)* – In the proposed rule, we stated that this level of service is defined by, when medically necessary, the administration of at least three different medications or the provision of one or more of the following ALS procedures:

- Manual defibrillation/cardioversion.
- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.
- Chest decompression.
- Surgical airway.
- Intraosseous line.

d. Specialty Care Transport (SCT) – In the proposed rule, we stated that this level of service is defined by, when medically necessary, for a critically injured or ill beneficiary, a level of interhospital service furnished beyond the scope of the paramedic as defined in the National EMS Education and Practice Blueprint. We stated that this service would be necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area (for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training).

e. Paramedic ALS Intercept (PI) – In the proposed rule, we stated that these services would be defined in § 410.40(c) "Paramedic ALS Intercept Services." These are ALS services furnished by an entity that does not provide the ambulance transport. Under limited circumstances, Medicare payment may be made directly to the entity furnishing paramedic services. (To obtain additional information about paramedic ALS intercept services, please refer to the March 15, 2000 final rule (65 FR 13911).)

f. Fixed Wing Air Ambulance (FW) – In the proposed rule, we stated that fixed wing air ambulance services would be covered when the point from which the beneficiary is transported to the nearest hospital with appropriate facilities is inaccessible by land vehicle, or great distances or other obstacles (for example, heavy traffic) and the beneficiary's medical condition is not appropriate for transport by either BLS or ALS ground ambulance.

g. Rotary Wing Air Ambulance (RW) – In the proposed rule, we stated that rotary wing (helicopter) air

ambulance services would be covered when the point from which the beneficiary is transported to the nearest hospital with appropriate facilities is inaccessible by ground vehicle, or great distances or other obstacles (for example, heavy traffic) and the beneficiary's medical condition is not appropriate for transport by either BLS or ALS ground ambulance.

Comment: In the context of determining when payment would be made at the ALS rate versus the BLS rate, some commenters disagreed with the definitions provided in the National Emergency Medical Services Education and Practice Blueprint (the Blueprint), stating that State definitions and standards differed from this document. Some States license as paramedics individuals who have not completed all of the hours or modules required by the Department of Transportation's National Standard Paramedic Curriculum. Technically, these individuals would not be "trained to the level" of a paramedic as defined in the Blueprint and the resulting National Standard Paramedic Curriculum. Commenters suggested that the definition of a paramedic should be a person who is licensed by the State at an ALS level, regardless of whether the level of the training of the person meets the definition of "paramedic" as described in the Blueprint or National Standard Paramedic Curriculum.

Several commenters also noted that the definition of BLS is confusing regarding establishment of a peripheral intravenous (IV) line. They further commented that, in many States, BLS personnel are not permitted by State law to establish IV lines. To clarify the definition, the commenters recommended that we make it clear that, when an IV line is established by an ALS crew, this is an

ALS intervention that qualifies the trip as an ALS transport.

Response: As a basis for defining the levels of service in the proposed rule, we incorporated the knowledge and skills outlined in the Blueprint. After considering the observations made by commenters and recognizing that the Department of Transportation, National Highway Traffic and Safety Administration has agreed to revise the Blueprint in the near future, we concluded that the knowledge and skill levels outlined in the Blueprint may be contrary to some existing State training standards and requirements. We have chosen instead, to rely on vehicle staffing requirements contained in existing State and local laws. Therefore, we are revising § 414.605 to indicate that payment will be made at the ALS1 level if the service furnished is beyond the skill level of an EMT-Basic in accordance with State and local laws.

Comment: Several commenters noted that the definition of ALS1 differed from that in the Committee Statement. Specifically, the conjunction used in the Committee Statement between "assessment by an advanced life support (ALS) ambulance provider or supplier" and "the furnishing of one or more ALS interventions" was "and/or" rather than "and." In addition, commenters pointed out that the ALS2 definition differed slightly between the preamble of the proposed rule and the proposed regulation text. For ALS2, commenters addressed the Committee Statement definition which was based on the supplier's provision of "three different medications *or* the provision of one or more of the following ALS procedures:

- Manual defibrillation/cardioversion.
- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.
- Chest decompression.
- Surgical airway.
- Intraosseous line."

The proposed definition at § 414.605 stated "three different medications *and* the provision of one or more of the following ALS procedures:

- Manual defibrillation/cardioversion.
- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.
- Chest decompression.
- Surgical airway.
- Intraosseous line."

Response: We agree with the commenters that the conjunction was inconsistent with the Committee Statement and, therefore, we are revising the regulation text to be consistent with the Committee Statement. We note, however, that we are using the conjunction "or" because this term carries the same meaning as "and/or."

Comment: Many commenters stated that the proposed definition of ALS assessment is confusing. The definition states that the ALS assessment is one "performed

by an ALS crew that results in the determination that the beneficiary's condition requires an ALS level of care." The commenters stated that, in order to be consistent with the Committee Statement, the definition should state that an ALS assessment is one performed by an ALS crew to determine whether the beneficiary's condition requires an ALS level of care. Some commenters suggested that the definition should be revised as follows: "'Advanced Life Support (ALS) assessment' is an assessment of a beneficiary with a medical condition requiring assessment by an ALS crew to determine whether ALS interventions are needed or may be needed during transport."

Response: We agree, and we have clarified the definition of ALS assessment accordingly. We are also clarifying that the ALS assessment is relevant only in an emergency case. While the Committee Statement is silent on this point, we believe that the ALS assessment would not be required in non-emergency or scheduled situations.

Comment: Many commenters stated that we should provide payment for all drugs, both low and high cost. Commenters stated that we had refused to negotiate on the issue of a separate payment for drugs in addition to and apart from the fee schedule payment for the ambulance transport, on the grounds that all drug costs should be included in the base rate. The commenters believe that this position fails to take into account the fact that many ambulance systems are now being forced to pay for drugs that were previously paid for outside of the Medicare payment. These costs, they argue, were not captured in the aggregate ambulance payment amount which we calculated and upon which we would calculate the CF. Therefore, they argue, these costs would not be reflected in the base rates. One way drugs were paid for in the past

outside the Medicare ambulance benefit was that a hospital would restock the ambulance without charge for any drugs that had been used. Commenters argue that, if hospitals do not continue restocking, ambulance suppliers will have to bear the cost of these drugs from a base rate that the commenters believe is already too low. The commenters believe that we should allow separate payments for drugs in addition to the ambulance fee schedule payment.

Response: Medicare's drug benefit does not permit a discrete payment for drugs furnished on board an ambulance. Drugs in ambulances have been included in ambulance payment only because they have been considered to be ambulance supplies. The law permits payment for a drug furnished on board an ambulance only if the drug is considered an element of the ambulance service. At the same time, the law does not permit payment under the ambulance benefit other than through the ambulance fee schedule.

As noted above, the BBA required that total payments during the first year of the fee schedule be no more than what would have been paid if the ambulance fee schedule were not in effect. The law provides no means to increase program payments for ambulance services that use new high-cost drugs. It provides only the inflation factor to increase rates under the ambulance fee schedule. With this constraint in mind, the Committee considered, within the structure of the fee schedule, establishing a separate RVU for drugs provided as ambulance supplies above a certain threshold cost. However, the Committee rejected this option. Therefore, payment for these items is included in the base rates for all levels of service.

Comment: Commenters questioned whether oxygen, saline and aspirin are considered medications for purposes of meeting the alternate criterion for the ALS2 level of service that the ambulance supplier provide three different medications.

Response: The proposed definition for an ALS2 level of service provides that this level of service is defined by, when medically necessary, the administration of at least three different medications or the provision of one or more of the following ALS procedures:

- Manual defibrillation/cardioversion.
- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.
- Chest decompression.
- Surgical airway.
- Intraosseous line.

Only medications requiring a higher level of skill to administer are considered medications for purposes of this definition. We are clarifying in the final rule that payment at the ALS2 level requires the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (for example, Dextrose, Normal Saline, Ringer's Lactate). Therefore, oxygen, saline and aspirin are not considered as medications for the purpose of determining whether an ALS2 level of care has been furnished.

Comment: Many commenters wanted to know whether three doses of the same medication on one transport warrant classifying the service as an ALS2 service.

Response: Three separate administrations of the same medically necessary medication (of the kind specified in the criteria for ALS2) during a single transport qualifies for payment at the ALS2 level.

Comment: Many commenters requested clarification regarding SCT. In particular, the commenters asked that we further define the phrase "paramedics with additional training." A commenter suggested that we include a reference to any State or local standards or protocols that define SCT training above and beyond the paramedic curriculum and a reference to a curriculum approved by the medical director of an EMS or ambulance system and shared with the carrier.

Response: As indicated in the response concerning the Blueprint, above, we are revising § 414.605 to indicate that vehicle staffing must be in compliance with existing State and local laws. We now define "paramedics with additional training" in terms of State or local authority that governs the licensing and certification of EMS personnel in the State in which a paramedic is licensed. It seems possible, even likely that there is no comparable definition in every State.

Comment: Some commenters asked whether the code for the SCT level service may be used as a code for a trip from a facility to an air ambulance and from the air ambulance to the final facility destination.

Response: Yes, the SCT level of service may be used in transporting a beneficiary from the hospital to an air

ambulance and then from the air ambulance to the second hospital, if the SCT criteria are met.

Comment: Some commenters believe that paramedic intercept services will suffer because of the failure in the fee schedule to recognize paramedic intercept in States other than New York as a cost-effective means of the delivery of prehospital care. Commenters stated that it is important to provide adequate payment for paramedic intercept in all areas of the country.

Response: As described in the regulations in § 410.40(c) (and also in Program Memorandum B-00-01 issued in January, 2000), under the Medicare statute, payment may be made directly to the intercept supplier for intercept services only if –

(a) The intercept service is provided in a rural area under a contract with one or more volunteer ambulance services;

(b) The volunteer ambulance supplier is certified to provide ambulance services;

(c) The volunteer ambulance supplier provides services only at the BLS level at the time of the intercept; and

(d) The volunteer ambulance supplier is prohibited by State law from billing anyone for the service furnished. The entity providing the intercept services must also be qualified to provide services under Medicare and must bill all patients receiving its intercept services.

At this time, to the best of our knowledge, only the State of New York has areas that meet these four criteria. In all other areas, the BLS level ambulance supplier must

bill the program for an appropriate level of service. If the paramedic intercept supplier wants to receive payment, it would have to make an agreement with the volunteer supplier regarding payment.

Comment: One commenter asked whether the new levels of ALS2 and SCT under the fee schedule would be blended with the current ALS emergency code payment rates during the transition period.

Response: For both ALS2 and SCT, the "old" portion of the blended amount is the allowance for ALS emergency services.

2. Emergency Response Adjustment Factor

We proposed to add § 414.610(c)(1) to state that, for the BLS and ALS1 levels of service, an ambulance service that qualifies as an emergency response service would be assigned higher RVUs to recognize the additional costs incurred in responding immediately to an emergency medical condition. An immediate response is one in which the ambulance supplier begins as quickly as possible to take the steps necessary to respond to the call. No emergency response adjustment factor applies to PI, ALS2, SCT, FW, or RW.

Comment: Some commenters stated that the definition of "emergency response" for purposes of the fee schedule in the implementing instructions (Program Memorandum AB-00-88) is inconsistent with the definition in the proposed rule and with the definition in the Committee Statement. The definition in AB-00-88 is:

An emergency response is one that, at the time the ambulance supplier is called, is provided after the sudden

onset of a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in placing the beneficiary's health in serious jeopardy; in impairment to bodily functions; or in serious dysfunction to any bodily organ or part.

The definition in the Committee Statement is:

For the BLS and ALS1 levels of service, an ambulance service that qualifies as an emergency response will be assigned a higher relative value to recognize the additional costs incurred in responding immediately to an emergency medical condition. An immediate response is one in which the ambulance provider begins as quickly as possible to take the steps necessary to respond to the call. There is no emergency modifier for PI, ALS2, or SCT.

Response: We agree with the commenter, and we will be changing the definition of "emergency response" in the final regulation to conform to the definition in the Committee Statement with one exception. We have decided to delete from the Committee Statement's definition the phrase "emergency medical condition" because the purpose of the higher payment for the emergency medical condition is to recognize the additional cost required in order to be prepared to respond immediately to a call (for example, from a "911" service) when it is received without regard to the condition of the beneficiary. The nature of the beneficiary's condition is considered in determining whether an ambulance transport was medically necessary and in determining the level of service (for example, BLS-Emergency, ALS1-Emergency or ALS2). However, the emergency rate is paid based on the immediate response to the 911-type call and not based on the services furnished to

the beneficiary. Therefore, we are revising the definition as follows:

Emergency response means responding immediately at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance supplier begins as quickly as possible to take the steps necessary to respond to the call.

We note that the definition of "emergency response" here is intended only to describe the circumstances under which higher payment would be made for services and its use is limited to this context. It would have no effect on other program definitions of "emergency."

3. Operational Variations

We proposed to add § 414.610(a), which would state that the ambulance fee schedule applies to all entities that furnish ambulance services, regardless of type. All public or private, for profit or not-for-profit, volunteer, government-affiliated, institutionally-affiliated or owned, or wholly independent supplier ambulance companies, however organized, would be paid according to this ambulance fee schedule, with the exception of CAHs as discussed above.

4. Regional Variations

a. Cost of living differences

In our proposed rule, we proposed that the payment for ambulance services would be adjusted to reflect the varying costs of conducting business in different regions of the country. We stated that we would adjust the payment

by a geographic adjustment factor (GAF) equal to the practice expense (PE) portion of the geographic practice cost index (GPCI) for the Medicare physician fee schedule. (For purposes of this document, we use the abbreviation "GPCI" to mean the PE portion of the GPCI.) The GPCI is an index that reflects the relative costs of certain components of a physician's cost of doing business (for example, employee salaries, rent, and miscellaneous expenses) in one area of the country as compared to another. The geographic areas would be the same as those used for the physician fee schedule. (A detailed discussion of the physician fee schedule areas can be found in the July 2, 1996 proposed rule (61 FR 34615) and the November 22, 1996 final rule (61 FR 59494).)

We proposed that the GPCI would be applied to 70 percent of the base payment rate for ground ambulance services; this percentage approximates the portion of ground ambulance service costs that are represented by salaries. Similarly, we proposed that the GPCI would be applied to 50 percent of the base payment rate for air ambulance services. The GPCI would not be applied to the mileage payment rate. In addition, the applicable GPCI would be based on the geographic location at which the beneficiary is placed on board the ambulance.

We proposed to use the most recent GPCI; the physician fee schedule law requires that the GPCI be updated every 3 years. The latest revision became effective January 1, 2001. The updated data were published in the November 1, 2000 final rule on the physician fee schedule (65 FR 65585).

Comment: A few commenters stated that the practice expense portion of the physician fee schedule GPCI does

not properly reflect the cost of living when calculating payment for ambulance services.

Response: We proposed using the practice expense portion of the GPCI, as described in the physician fee schedule final rule published in the **Federal Register** on November 1, 2000 (65 FR 65585). We based our proposal on the Committee Statement that using the PE of the GPCI is the most appropriate means available to measure the geographic differences in the costs of providing ambulance services. The components of the PE portion of the GPCI (for example, personnel and supplies) are similar to the components of ambulance services and the geographical variations in these costs for ambulances would therefore be similar to the cost variations for physician practices. Also, based on data available to the Committee, it recommended, and we agree, that the labor share of the costs of ambulance services is approximately 70 percent of the ground and 50 percent of the air ambulance cost. Therefore, the GPCI will apply to only 70 percent of the ground and 50 percent of the air ambulance base rates. We are not adjusting the mileage rates.

Comment: Some commenters believe that both legs of a round trip should be paid on the basis of the initial point of pick-up of the beneficiary, and that both legs of a scheduled round trip crossing GPCI or State lines should be billed to the carrier with jurisdiction for the initial point of pick-up. The commenters state that, given the proposed rule, suppliers may have to bill different carriers for each of two legs on the same round trip. Also, beneficiaries are likely to be confused by bills which indicate different charges for each leg of a round trip, if it does not begin in a rural area. Finally, rural suppliers could lose the rural adjustment for the second leg of a round trip.

Some commenters also believe the point of pick-up is not the best criterion for establishing level of payment. There were some commenters who felt that the GPCI should be matched to the location of the ambulance company. Also, some commenters wanted clarification on trips originating in another carrier jurisdiction.

Response: The Committee determined that the most equitable way to apply the GPCI, as well as the rural adjustment payment, was by the point of pick-up and not by the destination, location of the ambulance company, or where the ambulance is garaged. One concern identified by the Committee with using the location of the company or the place where the ambulance is garaged was the relative ease of moving the location of the company or garage to achieve higher payment. A second issue was that any individual trip in a rural area would likely be longer and prevent an ambulance from furnishing an additional trip, thereby reducing utilization, whether the ambulance was garaged in an urban or rural area. Considering each leg of a round trip separately gives effect to the Committee's determinations. Moreover, considering each leg separately achieves administrative simplicity and greater administrative accuracy in making payments.

Comment: One commenter suggested that the Medicare hospital area wage index be used in place of the GPCI, since many of the ambulance providers are hospital-based.

Response: The Committee decided to use the GPCI, not the hospital area wage index. As stated above, the components of the ambulance service are more similar to the components of the PE portion of the GPCI than they are to the components of the hospital wage index. Also,

fewer than 15 percent of ambulance services furnished to Medicare beneficiaries are hospital-based, so we do not see the hospital wage index as more appropriate than the GPCI. Thus, we will continue to use the practice expense GPCIs from the physician fee schedule.

b. Services furnished in rural areas

We proposed to add § 414.610(c)(1)(v), which stated that, for ground ambulance services in rural areas, a 50 percent increase is applied to the mileage rate for each of the first 17 miles; the regular (urban) mileage allowance applies to every mile over 17 miles. For air ambulance services, we stated, in rural areas, that a 50 percent increase is applied to the total payment for air services, both mileage and base rate. We proposed the 50 percent rural increase for the first 17 miles in consideration of the circumstances of isolated, essential ambulance suppliers (that is, when there is only one ambulance service in a given geographic area) which may not furnish many trips over the course of a typical month because of a small rural population. While we recognize that this methodology is not sufficiently precise to limit the rural bonus payment to only those rural ambulances that are isolated, essential, low-volume (the definition of rural we are proposing is not as precise as other alternatives), we proposed an adjustment to increase the rate of payment for mileage if the location at which the beneficiary is placed on board the ambulance is located in a rural area. We proposed to define a rural area to be an area outside a Metropolitan Statistical Area (MSA) or a New England County Metropolitan Area, or an area within an MSA identified as rural, using the Goldsmith modification.

The Goldsmith modification evolved from an outreach grant program sponsored by the Office of Rural Health Policy of the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services. This program was created to establish an operational definition of rural populations lacking easy geographic access to health services in large counties with metropolitan cities. Using 1980 census data, Dr. Harold F. Goldsmith and his associates created a methodology for identifying rural census tracts located within a large metropolitan county of at least 1,225 square miles. However, these census tracts are so isolated by distance or physical features that they are more rural than urban in character. Additional information regarding the Goldsmith modification can be found on the Internet at *http://www.ruralhealth.hrsa.gov/Goldsmith.htm*.

We could not easily adopt and implement, within the constraints necessary to implement the fee schedule timely, a methodology for recognizing geographic population density disparities other than MSA/non-MSA. However, we will consider alternative methodologies that may more appropriately address payment to isolated, low-volume rural ambulance suppliers. Thus, the rural adjustment in this rule is a temporary proxy to recognize the higher costs of certain low-volume rural suppliers.

Several difficult issues will need to be resolved to establish more precise criteria for suppliers that should receive the rural adjustment. Examples of such issues include: (1) Appropriately identifying an ambulance supplier as rural; (2) identifying the supplier's total ambulance volume (because Medicare has a record only of its Medicare services); and (3) identifying whether the supplier is isolated, because some suppliers might not

furnish services to Medicare beneficiaries (thus, Medicare would have no record of their existence) and one of these suppliers might be located near an otherwise "isolated" supplier. Addressing these issues in some cases will require the collection of data that are currently unavailable. We intend to work with the industry and with the Office of Rural Health Policy to identify and collect pertinent data as soon as possible.

We stated in our proposed rule that the application of the rural adjustment would be determined by the geographic location at which the beneficiary is placed on board the ambulance. Under the proposed rule, the rural adjustment would have been made using the following methodology:

- Ground – A 50 percent add-on applied to only the mileage payment rate for the first 17 loaded miles and a 25 percent add-on applied to only the mileage payment rate for miles 18 through 50.

- Air – A 50 percent add-on applied to the base rate and to all of the loaded mileage.

Comment: Several commenters expressed concern that there should be a more precise definition of low-volume rural ambulance suppliers and that the rural payment rate should be higher. They suggested that we could use data from the Office of Rural Health (ORH) or the Administration on Aging that would give a more precise determination than the MSA/non-MSA classification. Another commenter suggested using any areas that are designated as rural by the State. One commenter suggested that until a better rural adjustment is implemented, rural suppliers and providers should be paid under their current payment methodologies.

Response: We are exploring alternative means for identifying low-volume rural suppliers. We are exploring data from other sources, including the ORH, which has sponsored a study, Rural-Urban Commuting Areas (RUCA). This study was performed by the University of Washington Rural Health Research Center. We anticipate that a more precise definition of low-volume rural suppliers will reduce the number of suppliers who qualify for the higher rural payment, allowing us to better target the payment increases to these suppliers while adhering to the aggregate payment limit provided in the law. We do not have the legal authority to exempt rural ambulance services from the fee schedule and pay them under the current methodology with the exception of certain CAHs. (See discussion of section 205 of BIPA.) In addition, BIPA provided that the payment rate for rural ambulance mileage greater than 17 miles and up to 50 miles be increased by not less than one-half of the additional payment per mile established for the first 17 miles of a rural ambulance trip.

Comment: A few commenters suggested that we adopt a more precise means of identifying rural areas for the fee schedule, using zip codes rather than MSAs as the basis for identification.

Response: We are currently using zip codes to identify areas. However, we identify all zip codes as urban or rural, based on whether the zip code is located in an MSA or not, including the Goldsmith modifications. The zip code is the basis for determining point of pick-up and the payment of claims. As stated above, we are examining other alternatives for identifying rural and urban areas more precisely.

Comment: Some commenters asked if the rural modifier applies if the supplier bills less than $5 for mileage.

Response: The law requires that payment be based on the lower of the fee schedule amount or the actual charge. If the supplier/provider's charge for mileage is less than the rural mileage fee schedule amount, then payment is based on the lower actual billed amount.

Comment: One commenter suggested that we double the payment to small, rural hospital ambulance providers in the following categories: sole community provider hospitals, hospitals eligible for the CAH program, and hospitals under 100 beds.

Response: The Committee Statement does not include such a provision, and we would point out that, because of the requirements of section 1834(l)(3) of the Act, increased payments under such a provision would need to be offset by reduced payments to other ambulance providers and suppliers. Moreover, there is no authority to exempt these small rural hospitals from the fee schedule except as provided by the Congress in section 205 of BIPA. That section provides that only CAHs that are the only ambulance service provider/supplier within a 35-mile drive will be exempt from the fee schedule and will be paid based on their reasonable cost.

5. Mileage

We proposed adding § 414.610(c)(1)(iii) that would state that mileage would be paid separately from the base rate. The payment for mileage reflects the costs attributable to the use of the ambulance vehicle (for example,

maintenance and depreciation) which increase as the vehicle's mileage increases. Based on the Committee's agreement, the mileage rates for the base year 1998 would be as follows: $5 per mile for ground ambulance, $6 per mile for fixed wing ambulance, and $16 per mile for rotary wing ambulance. These rates will be adjusted by the ambulance inflation factor. However, payment for some mileage in rural areas is made at a higher rate as discussed in section II.A.4.b. of this final rule.

6. Structure of the Fee Schedule for Ambulance Services

We proposed in § 414.610(a) that the fee schedule payment for ambulance services would equal a base rate payment plus payments for mileage and applicable adjustment factors. (See Table 1 for a description of the structure of the ambulance fee schedule.)

7. Ambulance Inflation Factor

We proposed adding § 414.615, "Transition methodology for implementing the ambulance fee schedule," which would state that the ambulance fee schedule would include the ambulance inflation factor specified in section 1834(l)(3) of the Act (recently amended by BIPA) and discussed below.

8. Phase-in Methodology

We proposed adding § 414.615 that would provide for a 4-year transition period, as the result of the Committee agreement. (The phase-in schedule is described in section IV of this preamble.)

B. Proposed Changes Not Based on Negotiated Rulemaking

In the September 12, 2000 proposed rule, we proposed changes to certain policies that were not within the scope of the negotiated rulemaking process. These proposed changes were as follows:

1. Coverage of Ambulance Services

In § 410.40(b), we proposed revising the introductory language to provide a cross-reference to § 414.605 for a description of the specific levels of services. We proposed to revise paragraph § 410.40(d)(1) to state that transportation includes fixed wing and rotary wing ambulances. Also, we proposed revising § 410.40(d)(3) by adding two options to document medical necessity.

2. Physician Certification Requirements

On January 25, 1999, we published a final rule (64 FR 3637) that updated Medicare coverage policy concerning ambulance services. That final rule provided the documentation requirements for coverage of nonemergency ambulance services for Medicare beneficiaries. The rule requires ambulance suppliers to obtain, from the beneficiary's attending physician, a written order certifying the medical necessity of nonemergency scheduled and unscheduled ambulance transports. The final rule became effective February 24, 1999.

Our present regulations (at §§ 410.40(d)(2) and 410.40(d)(3)) set forth the requirements for scheduled and unscheduled nonemergency ambulance transports. The regulations require ambulance suppliers to obtain, from

the beneficiary's attending physician, a written physician statement certifying the medical necessity of requested ambulance transports.

Section 410.40(d)(3)(i) specifies that, in cases when a beneficiary living in a facility and under the direct care of a physician requires nonemergency, unscheduled transport, the physician's certification can be obtained up to 48 hours after transport. After publication of this rule, we were made aware of instances in which ambulance suppliers, despite having provided ambulance transports, were experiencing difficulty in obtaining the necessary physician certification statements within the required 48-hour timeframe.

While we still believe that the 48-hour timeframe is the appropriate standard, we recognize that there may be instances when, not through fault of their own, it may not be possible for the ambulance suppliers to meet the requirement. Therefore, we have determined that there is a need to revise and clarify this requirement (as described in § 410.40, "Coverage of ambulance services," paragraph (d)(3)).

We proposed that, before submitting a claim, the ambulance supplier must obtain –

(1) A signed physician certification statement from the attending physician; or

(2) If the ambulance supplier is unable to obtain a signed physician certification statement from the attending physician, a signed physician certification must be obtained from either the physician, physician assistant, nurse practitioner, clinical nurse specialist, registered nurse, or discharge planner who is employed by the

hospital or facility where the beneficiary is being treated and who has personal knowledge of the beneficiary's condition at the time the transport is ordered or the service was furnished (the term "physician certification statement" will also be applicable to statements signed by other authorized individuals); or

(3) If the supplier is unable to obtain the required statement as described in (1) and (2) above within 21 calendar days following the date of service, the ambulance supplier must document its attempts to obtain the physician certification statement and may then submit the claim. Acceptable documentation must include a signed return receipt from the U.S. Postal Service or similar delivery service. A signed return receipt will serve as documentation that the ambulance supplier attempted to obtain the required physician certification statement from the beneficiary's attending physician.

In all cases, the appropriate documentation must be kept on file and, upon request, presented to the carrier or intermediary. It is important to note that the presence of the signed physician certification statement does not necessarily demonstrate that the transport was medically necessary. The ambulance supplier must meet all coverage criteria in order for payment to be made.

Comment: Several commenters, including a national ambulance association and an association representing medical professionals, state that the proposed regulation permits physician certification statements to be signed by physician assistants (PA), nurse practitioners (NP), and clinical nurse specialists (CNS), but only if employed by the facility in which the beneficiary is being treated. The

commenters state, however, that, in most cases, practitioners are employed not by the facility but by the attending physician. The commenters recommended that the requirements of § 410.40(d)(3)(iii) be revised to specify that, in keeping with Medicare regulations, the PA, NP, or CNS may also be employed by the attending physician.

Response: We agree with the commenters and are revising § 410.40(d)(3)(iii) to clarify that the PA, NP, or CNS may be employed either by the facility or by the beneficiary's attending physician.

Comment: Many commenters recommended that we revise § 410.40(d)(3)(iv) to conform to Program Memorandum B-00-09 that clarified the circumstances under which a physician certification is required for both scheduled and unscheduled transports.

Response: Program Memorandum B-00-09 was issued in response to an inquiry that specifically addressed the 48-hour time requirement set forth in § 410.40(d)(3)(i). The program memorandum specifies that, in cases where a beneficiary who is living in a facility and who is under the direct care of a physician requires nonemergency, unscheduled transport, the physician's certification can be obtained 48 hours after transport has been provided. Based on comments, we are, however, revising the regulation to clarify that § 410.40(d)(3) is applicable to nonrepetitive, nonemergency, scheduled ambulance services. In specifying that the rule applies to nonrepetitive transports, we are aware that § 410.40(d)(2), as currently written, contains a requirement that suppliers obtain the required documentation no earlier than 60 days before the date the service is furnished. We are revising § 410.40(d)(2) to clarify that the 60-day requirement is

applicable only to repetitive transports, not nonrepetitive ones.

Comment: Many commenters, including a national ambulance association, expressed a concern that carriers may be interpreting the revised definition of "bed confined" to mean that the beneficiary be bed-confined even in cases where the medical condition of the beneficiary would otherwise indicate that transportation by means other than ambulance would be contraindicated. The commenters recommended that § 410.40(d)(1) be revised as follows:

For nonemergency transportation, transportation by ambulance is appropriate if the beneficiary is bed-confined or if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. In determining whether a beneficiary is bed-confined, the following criteria must be met:

(i) The beneficiary is unable to get up from the bed without assistance.

(ii) The beneficiary is unable to ambulate.

(iii) The beneficiary is unable to sit in a chair or wheelchair.

Response: In the June 17, 1997 proposed rule (62 FR 32719), these three criteria were developed to define bed-confinement. These criteria identify individuals who may need ambulance services: we identified as bed-confined only those individuals who are "completely confined to bed and unable to tolerate any activity out of bed." Subsequent instructional guidelines (PM AB-99-53, AB-99-83, AB-00-103) were issued in an effort to clarify that the bed-confined criteria are not meant to be the sole criteria in determining medical necessity; bed-confinement is one

factor to be considered. It is important that all factors relating to the beneficiary's condition are considered in evaluating whether the medical necessity criteria for ambulance services have been met. As always, it is the responsibility of the ambulance supplier to furnish complete and accurate documentation of the beneficiary's condition to demonstrate that the ambulance service being furnished meets the medical necessity criteria.

It is not our intent either to require that the bed-confined condition be met in every case in order for an ambulance transport to be covered or to mandate coverage of an ambulance transport solely because a beneficiary is bed-confined.

We agree with the commenters that our proposed revision was unclear. We are revising proposed § 410.40(d)(1). In addition to the identifying criteria on bed-confinement, the final rule will now state that:

For nonemergency ambulance transportation, transportation by ambulance is appropriate if the beneficiary is bed-confined and it is documented that the beneficiary's medical condition is such that other methods of transportation are contraindicated, or if his or her medical condition, regardless of bed-confinement, is such that transportation by ambulance is medically required. In determining whether a beneficiary is bed-confined, the following criteria must be met: * * *

3. Payment During the First Year

As explained below in more detail, we stated that we would use the universe of claims paid in 1998 (reduced by the $65 million savings that would have been realized

through implementation of the BLS and ALS definitions proposed in the June 17, 1997 proposed rule (62 FR 32718)) to establish the CF and would index the 1998 dollars to CY 2002 dollars using the compounded inflation factors derived from section 1834(l)(3) of the Act. (The transition and the inflation factors are described in § 414.615.)

4. Billing Method

In proposed § 414.610, we stated that, after the transition period, we would bundle into the base rate payment all items and services furnished within the ambulance benefit. This would eliminate billing on an itemized basis for any items and services related to the ambulance service (for example, oxygen, drugs, extra attendants, and EKG testing). In addition, only the base rate code and the mileage code would be used to bill Medicare. (This decision was made in accordance with section 1834(l)(7) of the Act, which gives us the authority to specify a uniform coding system, as well as with section 1834(l)(2)(B) of the Act.) During the transition period, suppliers who currently use billing methods 3 or 4 may continue to bill for supplies separately (see section I.B. for a description of these billing methods).

5. Local or State Ordinances

In proposed § 414.610, we stated that, regardless of any local or State ordinances that contain provisions on ambulance staffing or furnishing of all ambulance services by ALS suppliers, we would pay the appropriate ambulance fee schedule rate for the services that are actually required by the condition of the beneficiary. We proposed

this policy pursuant to the Medicare statutory requirement (see section 1834(l)(2)(B) of the Act) to use definitions of services that link payments to the types of services furnished.

6. Mandatory Assignment

In proposed § 414.610, we stated that, effective January 1, 2001, all payments for ambulance services must be made on an assignment-related basis, as mandated by section 1834(l)(6) of the Act. Ambulance suppliers must accept the Medicare allowed charge as payment in full and not bill the beneficiary any amount other than unmet Part B deductible or coinsurance amounts. There is no transitional period for mandatory assignment.

Comment: One commenter asked whether the fee schedule and mandatory assignment apply when Medicare is the secondary payer.

Response: Yes, both the ambulance fee schedule and mandatory assignment apply when Medicare is the secondary payer.

Comment: Several commenters objected to the requirement of mandatory assignment for claims when the fee schedule is implemented. They claim that because the rates in some areas are so low, some ambulance suppliers will go out of business without balance billing. One commenter indicated that we have the discretion to delay implementation of mandatory assignment until the end of the phase-in period. The commenter also requested clarification that mandatory assignment pertains only to services that are covered by Medicare.

Response: Mandatory assignment is required by section 1834(l)(6) of the Act. We do not agree that there is discretion to delay its implementation until the fee schedule is fully phased-in. The implementation date given in the proposed rule will be changed to coincide with the actual implementation of the fee schedule. Historically, ninety-five percent of ambulance services have been submitted under assignment, and, while the fee schedule redistributes payments, we do not anticipate that the assignment requirement is a major issue nationally. It is correct that mandatory assignment pertains only to Medicare covered services.

Comment: Some commenters asked whether the provider/supplier may bill the beneficiary for the non-covered charges for transportation to a facility beyond the nearest appropriate facility, or whether mandatory assignment prevents the provider/supplier from billing for this additional mileage.

Response: Mandatory assignment does not preclude billing for this additional mileage. Mandatory assignment refers only to services that are covered by the Medicare program.

Comment: Some commenters asked about the correlation between "Medicare+Choice" (M+C) plan payments and the ambulance fee schedule. The commenters asked if the amount paid by M+C plans is affected by the fee schedule amounts and if the liability of M+C enrollees is affected by the mandatory assignment requirement for the fee schedule.

Response: For ambulance services that are under contract with the plan, Medicare rates do not affect the payment amounts by the M+C or the enrollee's copay. For

ambulance services that are not under contract (for example, out-of-area emergency transports), the M+C is liable for the Medicare allowance in that area less any copay that the beneficiary pays pursuant to the M+C plan's rule for coinsurance.

7. Miscellaneous Payment Policies

The following payment policies were in effect before publication of the proposed rule; however, we used the proposed rule as an opportunity to clarify them.

a. Multiple Patients

Occasionally, an ambulance will transport more than one patient at a time. (For example, this may happen at the scene of a traffic accident.) In this case, we proposed to prorate the payment as determined by the ambulance fee schedule among all of the patients in the ambulance. If two patients were transported at one time, and one was a Medicare beneficiary and the other was not, we would make payment based on one-half of the ambulance fee schedule amount for the level of medically appropriate service furnished to the Medicare beneficiary. The Medicare Part B coinsurance, deductible, and assignment rules would apply to this prorated payment.

Similarly, if both patients were Medicare beneficiaries, payment for each beneficiary would be made based on half of the ambulance fee schedule amount for the level of medically appropriate services furnished to each beneficiary. The Medicare Part B coinsurance, deductible, and assignment rules would apply to these prorated amounts.

Comment: Some commenters disagree with our paying only the rate for one trip if two patients are transported. The commenters contend that it is not true that transporting two or more patients in the same vehicle costs no more than transporting one patient. Additional time will be required to load and unload each patient. Each patient will require specific individual care. The supplier will also incur additional liability for each patient for whom it is responsible. The commenters believe that one mileage fee should be paid, but that two base rates should be paid.

Response: With respect to multiple patient transports, we agree with the commenters that there would be, on average, a higher cost for multiple patient transports than for those with only a single patient onboard. While commenters stated that an extra attendant would be onboard and additional supplies would be used for multiple patients, we do not believe this would always be true. Therefore, if two patients are transported simultaneously, for each Medicare beneficiary we will allow 75 percent of the payment allowance for the base rate applicable to the level of care furnished to that beneficiary. If three or more patients are transported simultaneously, then the payment allowance for the Medicare beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary. However, a single payment allowance for mileage would continue to be prorated by the number of patients onboard. Also, we are establishing a modifier to identify these claims.

b. Pronouncement of Death

In the proposed rule, we stated that there are three rules that apply to ambulance services and the pronouncement of death. First, if the beneficiary was pronounced dead by an individual who is licensed to pronounce death in that State prior to the time that the ambulance is called, no payment would be made. Second, if the beneficiary is pronounced dead after the ambulance is called but before the ambulance arrives at the scene, payment for an ambulance trip would be made at the BLS rate, but no mileage would be paid. Third, if the beneficiary is pronounced dead after being loaded into the ambulance, payment would be made following the usual rules (that is, the same level of payment would be made as if the beneficiary had not died).

Comment: Some commenters suggested that we pay at the ALS rate if the crew attempts to resuscitate, even though they may fail. Also, some commenters believe that the pronouncement of death needs to be clarified further, so that unnecessary transportation will be limited.

Response: Program payment may be made only for medically necessary ambulance transports. There is no basis for us to pay under the ambulance benefit for services such as attempts to resuscitate, if no ambulance transport occurs. In this final rule, we are setting forth the following criteria to apply in the pronouncement of death:

- If the beneficiary is pronounced dead by an individual who is authorized by the State to pronounce death prior to the time the ambulance is called, no payment will be made.

- If the beneficiary is pronounced dead by an individual who is authorized by the State to pronounce death prior to the arrival of the ambulance, but after it is called, a BLS base rate payment will be made (except for air, as noted in the comment and response below). No payment for mileage will be made.

- If the beneficiary is pronounced dead by an individual who is authorized by the State to pronounce death during the transport of the ambulance, the same payment rules apply as if the beneficiary were alive.

Comment: Some commenters suggested that, in the case where a beneficiary dies while an air ambulance is enroute to the scene, we pay air ambulance at the air base rate, not the BLS ground rate.

Response: We agree with the commenters. We will not pay mileage because there is no transport, but we will pay the applicable air base rate.

c. Multiple Arrivals

We stated in the proposed rule that, when multiple units respond to a call for services, we would pay the entity that provides the transportation for the beneficiary. The transporting entity would bill for all services furnished, as stated in current policy. For example, if BLS and ALS entities respond to a call and the BLS entity furnishes the transportation after an ALS assessment is furnished, the BLS entity would bill using the ALS1 rate. We would pay the BLS entity at the ALS1 rate. The BLS entity and the ALS entity would have to negotiate between themselves payment for the ALS assessment.

Comment: Some commenters stated that the discussion of multiple arrivals in the proposed rule is confusing. They state that, although the issue was not discussed by the Committee, our discussion appears to be inconsistent with the industry's understanding that the ALS level of service may be billed only if an ALS supplier/provider is involved in the actual transportation.

Response: According to the definition of "ALS assessment" that we are promulgating in this final rule, an assessment may result in the determination that no ALS level service is required and, in that instance, an ALS1-Emergency level payment may be made to the transporting BLS ambulance supplier even if no ALS paramedic rides onboard.

Comment: One commenter stated that when two ALS ambulances respond, the ambulance fee schedule payment should be divided between them according to the services each provided.

Response: We have always construed the Medicare law as permitting payment for services only to the entity that provides the services, in this case, ambulance transport. Any suppliers that furnish services other than the transport must look to the transporting supplier for payment for other services. As described above, there is a limited provision of the law for paramedic intercept services under which the Congress permitted payment to be made directly to the entity furnishing the intercept service, but only under special circumstances provided in the regulations in § 410.40(c). However, a provider (for example, a hospital or skilled nursing facility) may furnish ambulance services under arrangements in accordance with section 1861(w) of the Act. In this case, the provider

may bill for the ambulance service, even if another supplier furnished the transport, if the service is furnished pursuant to an arrangement between the two entities in accordance with the law.

d. BLS Services in an ALS Vehicle

The proposed rule stated that effective with implementation of the fee schedule, claims would be paid at the BLS level where an ALS vehicle is used but no ALS level of service is furnished. Claims would be filed using the appropriate BLS code. Like the other rules describing levels of service, these rules would be applicable on the effective date of this rule; there would be no transitional period for the rule.

Comment: Several commenters stated that our decision to pay at the BLS rate for the use of an ALS vehicle when no ALS service is furnished has the effect of not recognizing all-ALS mandates by local authorities (situations where the local government mandates that all ambulances within its jurisdiction be equipped to provide an ALS level of service). The commenters stated that this policy, which will result in an immediate budget savings for Medicare of approximately $70 million in 2002, should be phased in on the same schedule as the other regulatory changes. The commenters believe that we should apply the transition provisions in the negotiated rule to all payment changes, including those stemming from our decision to pay BLS rates when BLS services are provided using an ALS vehicle. Because we did not propose to phase in this policy (that is, we are not continuing to pay at the ALS level under the old portion of the transition payment), the commenters believe that many emergency medical systems will be

threatened and Medicare beneficiaries will be at risk of not having access to emergency and other medical transportation services.

Response: While we continue to believe that BLS services should be paid at the BLS rate, even when an ALS vehicle is used, we agree with the comment to phase in the implementation of this policy. Therefore, when an ALS vehicle is used to furnish non-emergency BLS services only, the "old" portion of the blended rate will be at the "old" ALS non-emergency payment level and the "new" portion of the blended rate will be at the BLS fee schedule amount.

In addition, we are revising the definition of an ALS assessment needed to qualify for an ALS1-Emergency level of payment from the proposed definition. An emergency ambulance trip may be paid as an ALS1-Emergency even when the only ALS service furnished is an ALS assessment. This revision in the final rule will increase the trips paid at the ALS1-Emergency level, rather than at the BLS-Emergency level. Where the only ALS service furnished is an ALS assessment for an emergency, the "old" portion of the blended rate will be at the ALS emergency rate. We have also increased the amount of spending upon which the CF is based by the amount of savings that had been attributed to this policy.

III. Methodology for Determining the Conversion Factor

As discussed in the September 12, 2000 proposed rule (65 FR 55078), our approach to determining the conversion factor (CF) was:

(1) To use the most recent complete year of ambulance claims;

(2) To translate those claims into the format that would have been used under the fee schedule; and

(3) To calculate the CF, that, when applied to the RVUs for each level of service, results in the same total program payment for those claims, less $67 million that would have been saved if the fee schedule legislation had not been passed. (Under the final rule, as discussed in section III.D, we have decided not to subtract this amount in calculation of the CF.)

We would then inflate this CF in accordance with the inflation factor prescribed in the statute. (See section 1834(l)(3) of the Act, as amended by section 423 of BIPA.) We used 1998 as the base year because this was the most recent complete year for which claims data were available. For claims processed by carriers (that is, claims from independent ambulance suppliers), we used allowed charge data. For claims processed by fiscal intermediaries (FIs) for provider-based ambulance services, we used the submitted charges on the Medicare claims multiplied by the cost-to-charge ratio applicable to the ambulance costs for each provider.

We modified the claims data in several ways to calculate the proposed fee schedule and its impact. First, we separated all claims into two groups:

- Carrier-processed claims for ambulance services (8 million in 1998).

- FI processed claims for ambulance services (900,000 in 1998).

A. Carrier-Processed Claims

We had to adjust some of the 1998 claims for purposes of the proposed ambulance fee schedule calculation. Some of the claims did not report mileage and, because mileage will be required for each ambulance service under the fee schedule, an adjustment had to be made for the missing miles (see above). In other cases, the billing codes under the old system did not translate directly into services that would be paid under the proposed fee schedule. Below is a more detailed explanation of the adjustments that were made to the 1998 base year data in order to accommodate missing data.

1. Mileage

Approximately 1.1 million claims for ground ambulance services did not show any mileage. The proposed fee schedule for ambulance services will provide a payment for the trip and a payment per statute mile for the loaded mileage traveled. Therefore, in calculating the proposed CF, we added mileage to those claims that did not report mileage. We did so by assigning the mode value (that is, the number of miles billed most often) per trip in urban areas (1.0 miles) and the mode value or mileage per trip in rural areas (1.0 miles).

Current billing instructions provide that only one ambulance trip may be billed per line on a claim. Because billing rules prohibit more than one trip to be reported on a line, we assumed any number greater than one was an error. Therefore, we did not count multiple trips billed on the same line of a claim. This reduced the total trip count processed by carriers by approximately 1 percent. This reduction of about 1 percent in the number of trips

resulted in an increase of about 1 percent in the average allowed charge per trip.

Comment: Some commenters stated that some billers do not bill for mileage and will continue not to bill mileage after the fee schedule is implemented. Commenters stated that in other cases a supplier's submitted charge for mileage is lower than the fee schedule rural mileage rate and asked that the Medicare carrier automatically increase the supplier's charge by 50 percent before comparing the submitted charge to the fee schedule rural mileage rate. (This comparison is made because the law requires that payment be based on the lower of the actual submitted charge or the fee schedule amount.) Also, commenters stated that some billers have a lower charge for mileage that would offset their higher charge for the ambulance base rate service, but that this will not be considered when we process the claim for the base rate for purposes of the fee schedule.

Response: In the process of setting the conversion factor (CF), we found over one million claims that should have reported mileage but did not. As stated above, we assigned a value of 1 mile to each of these claims. This was the mode value of mileage for both urban and rural ambulance claims. The average value was 7 miles for urban and 17 miles for rural claims. Assuming 1 mile each for claims without mileage results in a higher CF than would have resulted if we used the average number of miles. We will monitor claims data after the fee schedule is initially implemented and recalibrate the CF to reflect actual, as opposed to projected, billing practices.

With respect to comments that we take into account suppliers that have high service charges but low mileage

charges, we do not believe that this result is necessary or practical. Section 1833(a)(1)(R) of the Act states that CMS pays the lower of "the actual charge for the services" or fee schedule. While some commenters argued that we should be comparing total charges (that is, base rate plus mileage) rather than looking at the service and mileage separately, we believe comparing the components of the charge is equally consistent with the law. Moreover, the entire Medicare claims processing system is set up to process claims on an individual line-item basis. To change the claims processing system would jeopardize timely implementation of the fee schedule.

Comment: Many commenters suggested that the urban/rural designation for round trips should be based on the original point of pick-up, rather than from each point of pick-up.

Response: Each trip consisting of a point of pick-up and a destination is considered to be a trip on its own and must be billed, processed and paid individually.

Comment: One commenter presented this hypothetical: beneficiary becomes ill on a cruise near Alaska. Beneficiary is airlifted. The nearest facility cannot adequately care for the beneficiary. The nearest facility that can adequately attend to the beneficiary is in Anchorage, Alaska. The beneficiary lives in the continental United States. The beneficiary requests to be sent to Seattle, Washington. Can this be done?

Response: The program covers mileage only to the nearest facility equipped to treat the beneficiary. Any additional mileage is not covered by Medicare. However, the beneficiary may arrange with the ambulance supplier to pay the difference.

2. Billing Codes

We determined that the billing codes that represent items and services included under the ambulance fee schedule are all billing codes submitted by ambulance suppliers in the range of Health Care Common Procedure Coding System (HCPCS) A0030 through A0999 (excluding HCPCS code A0888, which is not covered by Medicare) and Common Procedural Terminology-Fourth Edition (CPT-4)[1] codes 93005 and 93041. HCPCS billing codes A0030 through A0999 represent ambulance services, supplies, and equipment that are covered by the ambulance fee schedule, and CPT codes 93005 and 93041 represent electrocardiogram (EKG) services that may be billed by ambulance suppliers. In addition, we incorporated all HCPCS billing codes in the range of A4000 through Z9999; these services could have been paid by a carrier to an ambulance supplier only if they represented items and services covered under the Medicare ambulance benefit. We excluded all other CPT billing codes in the range of 00001 through 99999 (except the two EKG codes listed above) because they represent services not covered by the ambulance fee schedule.

Next, we adjusted all billing codes that represented an ALS vehicle when no ALS service was furnished. We removed the actual allowed charges on these claims and replaced them with the charges that would have been allowed by the carrier for the corresponding BLS level of service (that is, emergency for emergency and nonemergency for nonemergency).

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[1] CPT codes and descriptions only are copyright 2001 of the American Medical Association. All Rights Reserved. Applicable FARS/DFARS Apply.

Comment: Several commenters stated that our decision to pay at the BLS rate for the use of an ALS vehicle when no ALS service is furnished has the effect of not recognizing all-ALS mandates by local authorities (situations where the local government mandates that all ambulances within its jurisdiction be equipped to provide an ALS level of service). The commenters stated that this reduction in the amount of spending used to set the CF was inappropriate.

Response: While we continue to believe that BLS services should be paid at the BLS rate, even when an ALS vehicle is used, we have decided to increase the amount of spending upon which the CF is based by the amount of savings that had been attributed to this policy.

3. Crosswalking the Old Billing Codes to the New Billing Codes

We converted the old billing codes in the base year data to the new billing codes as they will be under the final fee schedule. The old BLS codes convert directly to the final BLS codes. The old air ambulance codes (fixed wing and helicopter) convert to the final air ambulance codes. The old water ambulance code converts to the final BLS-Emergency code. The old mileage codes distinguished ALS miles from BLS miles; both of these old codes will convert to the single proposed mileage code. Codes used to report air mileage will convert to the final codes for fixed and rotary wing mileage, respectively. All air miles will be reported in statute miles. As mentioned earlier, we converted the codes for an ALS vehicle when no ALS services were furnished to the corresponding BLS codes. The conversion of the remaining old ALS codes (for example, when ALS services were furnished) to final ALS codes is

less straightforward because there are more levels of ALS service under the final fee schedule than currently exist. All nonemergency ALS codes convert to the ALS1 (nonemergency) code. Based on advice from various members of the Committee, for purposes of calculating the CF, we proposed converting the old emergency ALS codes according to the following formulas:

- For claims on which both the origin and destination was a hospital: 33 percent will convert to specialty care transport (SCT), 5 percent to advanced life support, level two (ALS2), and the remainder to ALS1-Emergency.

- For all other claims: 8.3 percent will convert to ALS2, and the remainder to ALS1-Emergency.

Comment: Commenters stated that the projected volume of 8.3 percent of current ALS emergency claims that will be billed under the fee schedule at the ALS2 rate is too high. The commenters stated that the projection provided by the Committee was only 2.3 percent.

Response: This comment was in error. We have verified with the Committee that the 8.3 percent projection was correct.

4. Low Billers

A concern was raised about low billers of ambulance services. Low billers are suppliers who currently bill less than the maximum charge allowed by Medicare. There are several reasons low billers exist. For example, an entity may have a low charge because the cost of its operation is subsidized by local taxes (for example, a municipal ambulance company); the entity may use volunteers; its charge may be regulated by local ordinances, limited by an

inflation-indexed charge that is part of the Medicare program's current reasonable charge policy, or restricted for other reasons.

In the proposed rule, we stated that we have neither a means to estimate the extent to which low billing will continue after the fee schedule is implemented and the inflation-indexed charge limit no longer applies, nor a means to estimate the extent to which volunteer and municipal ambulances will choose not to file Medicare claims at the fee schedule amounts to which they could be entitled. Therefore, given the uncertainty of suppliers' future behavior, we proposed not to attempt to adjust the CF based on assumptions that low billing will or will not continue. We also stated that we will monitor payment and billing data and recalculate the CF as appropriate.

Because the total ambulance service payment amount is based on the actual allowed charges from the base year (1998), the CF will reflect historical charges for some suppliers that may have been lower than the reasonable charges of other suppliers. At the same time, if low billers of ambulance services continue to charge less than the ambulance fee schedule amount, we will continue to pay the lower amount as the law requires. Therefore, some members of the ambulance industry have urged us to increase the fee schedule CF, anticipating that, otherwise, savings would result from billers who continue to charge less than they could, in this case, less than the fee schedule amount. We have estimated that in the base year 1998, if all low billers had billed the maximum charges allowed by Medicare, total allowed charges for ambulance services would have been approximately $150 million more than they were. Approximately half of this amount is attributable to charges that are 70 percent of the maximum

allowed charges or greater. Assuming that billers whose current charge is 70 percent or more of the maximum will charge the full fee schedule amount and that one-half of the entities whose current charge is less than 70 percent of the maximum allowed charge may continue to bill at less than the fee schedule amount, approximately $39 million in the base year 1998 might continue to be attributed to low billing. Adjusted for inflation, this amount (annualized) is approximately $42 million in 2002.

Comment: We received many comments questioning our approach to low billers. In particular, commenters believe that we were calculating the CF in such a way that we would inappropriately achieve between $75 million and $150 million in savings by assuming all low billers would begin to bill at the full amount allowed under the fee schedule. Commenters stated that we were obligated to ensure that the implementation of the fee schedule was budget neutral.

Response: We believe some commenters misunderstood our reasoning when we referred to the fact that an approximately $150 million difference existed in 1998 between ambulance suppliers' actual charges and the maximum charges allowed by Medicare and that approximately half of this amount (about $77 million) is attributable to charges that are 70 percent of the maximum allowed charge or greater. For those suppliers already charging 70 percent or greater of the maximum charges allowed, our reasoning was that they are likely to increase their charges when the inflation-indexed charge limit no longer applies.

While we continue to believe that future billing behavior is unpredictable, we have decided to make an

adjustment in the CF in response to this comment. We will increase the CF to account for approximately $39 million in the base year 1998 (one-half of the amount attributable to the difference by which charges are less than 70 percent of the maximum allowed by Medicare ($77 million)). In light of the lack of available data to project how many low billers will increase their charges, we have decided to assume that one-half of the remaining low billers (representing the billers whose charge is less than 70 percent of the maximum) may continue to bill at less than the fee schedule because we agree that some low billers may not increase their charges up to the fee schedule amount. We will review this issue as part of the annual review to determine whether a further adjustment is warranted. If the level of low charge billing is significantly different from the assumed level, we will adjust the CF and apply such an adjusted CF prospectively. We also note that, in other circumstances, we have made assumptions that resulted in a higher CF. For example, as discussed above, in the process of setting the CF, there were over one million claims that should have reported mileage but did not. We assigned a value of one mile to each of these claims. This has resulted in a higher CF than if we had assigned a higher mileage estimate to these claims.

B. FI Processed Claims

Because all FI processed claims contained mileage, we did not make any adjustment for mileage. However, we did have to determine the codes that represented items and services included under the ambulance fee schedule. In the case of claims filed by hospital-based ambulance providers, services furnished in the emergency room and other

outpatient departments of the hospital are reported on the same claim that is used to report the ambulance service. Therefore, it is impossible to know from the claims data where any of the nonambulance services were furnished. Because most of these nonambulance services were of the kind that would likely have been furnished in the hospital's emergency room, we did not include the data on them in data for the proposed ambulance fee schedule. Rather, we determined that the billing codes that will be covered by the ambulance fee schedule are all billing codes representing ambulance services submitted by hospitals (for example, in the range of HCPCS codes A0030 through A0999 (excluding HCPCS code A0888, which is not covered by Medicare)).

Codes that represented the use of an ALS vehicle, but when no ALS level of service was furnished, were converted to the corresponding BLS billing code. However, in this case, no adjustment was made for payment because the correct data were already available since payment for these claims would have been made on a cost basis corrected to the proper amount at cost settlement.

Comment: A few commenters stated that the regulations do not address the issue of bad debt for ambulance services. Medicare has traditionally paid for hospitals' bad debts for uncollected beneficiary deductibles and copayments. The commenters believe that Medicare should be responsible for payment of reasonable costs associated with bad debt for ambulance services as well.

Response: There is no provision under the fee schedule for payment of bad debts. The law requires that the program pay 80 percent of the lower of the fee schedule amount or the billed charge and that the beneficiary is

liable for the Part B coinsurance and any unmet Part B deductible amounts. Furthermore, sharing in bad debts for providers and not for independent suppliers would result in greater program payments to providers than suppliers for furnishing the same service. We believe that doing so would be antithetical to payment under a fee schedule.

C. Air Ambulance

To establish a consistent system of RVUs that could be applied to ground and air ambulance services, we must know the cost per service in each setting. Unfortunately, these data do not exist. One member of the Committee presented data and stated that the data, when combined with an analysis by an economist, demonstrated that the total costs in 1998 for air ambulance services were between a minimum of approximately $134.8 million and a maximum of $168 million. The higher amount exceeded the billed charges for air ambulance services. Because definitive cost data do not exist, the Committee decided to compromise by setting a range of total air ambulance costs between $134.8 million and $158 million within which we would set an amount reflecting incurred costs.

We considered several approaches in an attempt to accurately estimate the appropriate amount for air ambulance services within the range prescribed by the Committee.

We considered using cost data from a ground ambulance services survey acquired by an independent source that was hired by a member of the Committee. We tried to compare the results of this survey to cost data from our estimate. Because the study was only a self-reporting survey and did not report audited costs, and because the

results varied widely and were substantially different from our estimate, we could not establish an estimate based on the survey that fell within the range prescribed by the Committee.

We converted old billing codes to the proposed billing codes in the same way as discussed above for the carrier-processed claims. Using the billed charge adjusted by the provider's cost-to-charge ratio, we are able to estimate the provider's Medicare-allowable cost for all ambulance services. However, we are unable to estimate with any certainty the split of air ambulance services costs and ground ambulance services costs from the same provider because Medicare cost-apportioning rules do not require data to be furnished in such detail. Originally, we assumed that the same cost-to-charge ratio within a provider applies to both air and ground ambulance services charges. However, because this assumption may not be correct, and because it results in an amount below the range specified by the Committee, we did not pursue this methodology.

Next, we considered using the billed charges for ambulance services. Over 80 percent of ground ambulance services are furnished by independent (not provider-based) ambulance suppliers. However, the average adjusted charge (that is, the charge adjusted by the provider's cost-to-charge ratio) for ALS and BLS ground ambulance services, excluding mileage, furnished by provider-based ambulance services is more than 65 percent greater than the average charge for independent ambulance services suppliers ($342 vs. $206 per trip). Assuming the appropriate payment for ground ambulance services is the average allowed charge for the independent suppliers, the amount

of money misallocated to provider-based ground ambulance services substantially exceeds the amount that would represent a total payment for air ambulance services at the maximum recommended by the Committee ($158 million). This large discrepancy between the payment rates for provider-based and independent supplier ground ambulance services, and the fact that suppliers are able to furnish services at the lower rate, led us to conclude that the program cost apportionment process caused too much of providers' ambulance costs to be allocated to provider-based ground ambulance services and not enough of these costs were allocated to provider-based air ambulance services. We believe that the appropriate payment for ground ambulance services is closer to the independent supplier charge. Consequently, we have chosen the maximum air ambulance total amount designated by the Committee, that is, $158 million.

Comment: A few commenters mentioned that the cap on per trip payment inflation imposed on providers by section 4531 of the BBA of 1997, which states that the Secretary shall not recognize the costs per trip in excess of costs recognized as reasonable for ambulance services provided on a per trip basis during the previous fiscal year increased for inflation, is currently applied as a combined cost per trip cap for both ground and air ambulance trips. This, they state, is inappropriate because the mix of air and ground trips may change from year to year. The commenter stated that there should be separate caps for ground and air ambulance trips.

Response: We have interpreted this provision of the law as requiring a single combined cost per trip inflation payment cap for providers, because the law refers to total

"costs per trip." We do not believe that the law contemplates the construction suggested by commenters. We also note that this issue arises only during the transition period. Once the fee schedule is fully implemented, there will be no provider-specific cost per trip limit.

Comment: A few commenters wanted further clarification on the methodology used to set the air ambulance fee schedule rates. Some commenters stated that the air ambulance payment rates should not be increased to the point of the air ambulance recovering its cost when payments for the ground ambulance will be reduced further to an amount below its cost. Another commenter stated that it is not reasonable to set the air amount based on charges for ground services.

Response: We do not have cost data to specifically distinguish the cost for air or ground services. The Committee recommended a range of $134.8-$158 million, and we determined the appropriate amount within that range. Because we believe that we have providers' total costs for all ambulance services, we chose to use a proxy for the approximate charge (average charge for independent suppliers) for ground and subtract that amount from the total provider ambulance cost to estimate an appropriate amount for the air cost portion.

Considering the large discrepancy between the payment rates for provider-based and independent supplier ground ambulance services, we believe that the appropriate payment for these ground ambulance services is closer to the independent supplier charge for the following reasons: (1) Over 80 percent of ground ambulance services are furnished by independent (not provider-based) suppliers, and (2) 95 percent of suppliers' claims are paid on an

assigned basis (that is, suppliers accept the Medicare allowed charge as payment in full). Consequently, we have chosen the maximum air ambulance total amount recommended by the Committee, which is $158 million. Choosing an amount lower than $158 million would lead us to pay ground ambulance rates at closer to the hospital-based rate than the independent supplier rate, which we believe to be unwarranted.

Comment: Some commenters cited abrupt and erratic increases in gas prices as a reason for the cost of air ambulance exceeding the proposed fee schedule rates. The impact will especially be felt for those providers whose aircraft consume from 60 to 103 gallons per hour.

Response: We believe that if increases in the cost of fuel occur, they will be accounted for by the inflation update factor applied to the ambulance fee schedule. We have set the rates for air at the maximum recommended by the Committee.

D. Calculation of the CF

We determined the total number of ambulance trips and loaded miles and the total amount of charges allowed by Medicare for ambulance services in the base year of 1998. In estimating the total volume of services at the new levels described under the fee schedule, we coded those cases in which an ALS vehicle was used in a nonemergency transport, but no ALS services were furnished, as BLS nonemergency services. Where an ALS vehicle was used in an emergency transport, we coded the transport as ALS1 if no ALS services were furnished because we assumed that an ALS assessment would always be

performed; under the fee schedule, the criteria for ALS1 includes such an assessment.

To calculate the CF for ground ambulance services, we used the following procedures:

- We multiplied the volume of services for each level of ground ambulance service by the respective RVUs recommended by the Committee (including application of the practice expense of the GPCI and of the rural mileage rate as described above).

- We summed those products to arrive at the total number of RVUs.

- We subtracted the total allowed amount for air ambulance services ($158 million as discussed above) from the total charges allowed by Medicare for ambulance services, which results in the total amount of charges allowed by Medicare for ground ambulance services.

- We subtracted the total amount of allowed charges for ground mileage from this total charge amount.

- We divided the remaining charge amount by the total number of RVUs for ground services and applied the cumulative ambulance inflation factor for the period 1998 through 2002, which results in a CF for ground ambulance trips of $170.54.

We made five (5) changes from the calculation of the CF described in the proposed rule (which was $157.52). First, at the time of the proposed rule, we failed to cross-walk the emergency cases in which an ALS vehicle was used, but no ALS service was furnished, to the category of ALS1-Emergency services under the fee schedule; instead, we counted them as BLS-Emergency services.

Second, there was a miscalculation of the number of rural ambulance miles that are less than or equal to 17 in the 1998 base data. Third, in this final rule, we added approximately $42 million (the annualized amount for 2002) as an estimate of the amount of low billing that will occur under the fee schedule and, thus, the amount that will be available for other ground ambulance services. This is discussed further in section V.B. Fourth, we changed the inflation adjustment for 2001 to conform to the inflation adjustments contained in section 423 of BIPA. Fifth, we added back to the total amount used to calculate the CF the savings that would have accrued to the program had we implemented the policy proposed in June 1997 that would pay at the BLS rate for services furnished at the BLS level even though an ALS vehicle was used.

We followed a similar procedure to determine the fee schedule amount for air ambulance services. Because there are only two kinds of air ambulance – fixed wing and rotary wing – we did not calculate RVUs and a CF, but calculated the actual fee schedule amounts directly. We divided the total number of billed air ambulance services into the total amount of payment available for these services ($158 million). The amounts in the base year (1998) are $2,286.52 and $2,658.42 for fixed wing and rotary trips, respectively. These numbers would then also be adjusted by the cumulative inflation factor provided in section 1834(l) of the Act. (The inflation factor is discussed in more detail below.)

We will monitor payment data and evaluate whether our assumptions used to establish the original CF (for example, the ratio of the volume of BLS services to ALS services) are accurate. If the actual proportions among the different levels of service are different from the projected

amounts, we will adjust the CF accordingly and apply this adjusted CF prospectively.

Comment: One commenter recommended a third air rate for air ambulance services furnished in remote, frontier areas such as Alaska. The commenter stated that the cost of furnishing these services is considerably higher than standard rural areas because of the sparse population and large distances that must be traveled.

Response: We are not making this change to the fee schedule. Consistent with the Committee Statement, there will be two air rates: fixed wing and rotary wing (helicopter). As explained under the section for rural modifiers, there will be a 50 percent add-on applied to the base rate and to all of the loaded mileage for air ambulance services in rural areas. Therefore, longer trips will be paid proportionately more than shorter trips.

Comment: Many commenters from various regions believe that the fee schedule rates are too low and that suppliers and providers will substantially lose profits. Some commenters suggested that, for various reasons, they should be exempt from the fee schedule and continue to be paid under the current system. For example, a commenter described the EMS system in New Jersey as unique and stated that placing New Jersey ambulance suppliers under the fee schedule would actually result in a higher cost to Medicare because it would ultimately force volunteer ambulance companies to close.

Response: Section 1834(l) of the Act requires that the Secretary establish a fee schedule for ambulance services through negotiated rulemaking. Although the statute does call for consideration of appropriate regional and operational differences in the design of the fee schedule, it does

not authorize exemptions or waivers for individual providers or suppliers or groups of those providers or suppliers. However, with the enactment of BIPA, the Congress created one limited exemption from the fee schedule – CAHs that do not have another ambulance supplier within a 35-mile drive.

The Congress required that the fee schedule be implemented in such a way that Medicare payments for ambulance services would not exceed what they would have been absent the new fee schedule. The fee schedule will increase payments for providers and suppliers with unusually low rates, and decrease payments for those who have historically received payments above the national average, while still accounting for geographic differences in costs and other factors. In anticipation of such shifts, the Congress provided for a phase-in period to allow ambulance providers time to adjust to the new payment rates.

IV. Implementation Methodology

Currently, payment of ambulance services follows one of two methodologies, depending on the type of ambulance biller. Claims from ambulance service suppliers are paid based on a reasonable charge methodology, whereas claims from providers are paid based on the provider's interim rate (which is a percentage based on the provider's historical cost-to-charge ratio multiplied by the submitted charge) and then cost-settled at the end of the provider's fiscal year.

In the September 12, 2000 proposed rule, we stated that the ambulance fee schedule would be phased in over a 4-year period. The transition was to begin on January 1,

2001 and the fee schedule was to be phased in on a CY basis. However, as explained above, we will implement the fee schedule beginning April 1, 2002. Therefore, for dates of service (DOS) beginning April 1, 2002, suppliers/providers would be paid based on 80 percent of the respective current payment allowance (as described in Program Memorandum AB-00-87) applicable to this time period plus 20 percent of the ambulance fee schedule amount. (See § 414.615 for additional information.) Based on comments received, we will phase-in implementation of the ambulance fee schedule under a 5-year transition, as follows:

	Former payment percentage	Fee schedule percentage
Year One (4/2002-12/2002)	80	20
Year Two (CY 2003)	60	40
Year Three (CY 2004)	40	60
Year Four (CY 2005)	20	80
Year Five (CY 2006)	0	100

Comment: Many commenters expressed concern over whether providers, suppliers, carriers, and CMS are fully prepared for the ambulance fee schedule implementation and whether all of the necessary steps to ensure successful implementation have been taken. Specifically, commenters believe there was insufficient time between the close of the comment period on November 13, 2000, and January 1, 2001, to:

- Educate intermediaries, carriers and all ambulance suppliers and beneficiaries in order to provide a smooth transition to the new system.

• Change our computer programs (and for suppliers to change theirs) and test these changes before placing them online.

The fee schedule creates new codes, new requirements (for example, zip code for point of pick-up), new levels of service, and a transition blending methodology. The commenters stated that neither suppliers nor beneficiaries will understand how they are to be paid. Several commenters requested that we delay the implementation from January 1, 2001, to a later date.

Response: Although the proposed rule was largely based on an agreement reached as part of a formal, negotiated rulemaking process with representatives of the ambulance industry and other interested parties, we received a large volume of comments. We did not have sufficient time to carefully consider all comments and publish a final rule in time to implement the fee schedule by January 1, 2001. Therefore, payment under the fee schedule structure (that is, a blend of fee schedule amounts and current payments) did not begin on that date. This has allowed suppliers additional time to adjust to the proposed payment methodology.

The proposed rule was published in the **Federal Register** on September 12, 2000 (65 FR 55078). Suppliers have also had access to the formal instructions we issued to contractors with respect to the systems changes necessary to implement the fee schedule. In addition, we held a training conference with intermediaries and carriers on November 16 and 17, 2000, on all issues related to the fee schedule. Contractors conducted training efforts directly with ambulance suppliers during December 2000. We will

continue our training efforts as we implement the new billing codes.

Comment: One commenter suggested that we cancel implementation of the ambulance fee schedule.

Response: We are required by the Congress under section 1834(l) of the Act to implement a fee schedule for ambulance services.

Comment: Two commenters stated that information in the Medicare and You publication was insufficient regarding the ambulance fee schedule.

Response: The *Medicare and You* publication is a handbook that provides a general synopsis of all services in Medicare: the level of detail concerning payment policy and implementation of the ambulance fee schedule in that publication are aimed at the general reader and not necessarily ambulance suppliers. Payment policies for ambulance services are published in detail in the **Federal Register** and subsequently in the CFR.

Comment: A few commenters disagreed with the phase-in schedule for the implementation of the ambulance fee schedule, stating that the implementation period was too short and not "in an efficient and fair manner" as required by the statute. The commenters stated that the phase-in is on a 3-year basis rather than a 4-year basis, as stated in the proposed rule. A few commenters wanted immediate, 100 percent implementation of the ambulance fee schedule, while others suggested other timeframes for a phase-in. Some commenters suggested a slower transition for providers as opposed to suppliers. Also, a few commenters recommended that SCT service payments be

fully and immediately implemented separately from the rest of the fee schedule.

Response: We agree that suppliers and providers need additional time to adjust to the fee schedule. Therefore, we will change the phase-in schedule from the proposed 4 years to a 5-year transition, as shown above. Thus, the overall phase-in is reflected in a 5-year span, with year 5 being at 100 percent of the fee schedule.

Comment: A few commenters requested that phase-in of the fee schedule should be by fiscal year for hospitals rather than by calendar year.

Response: We have decided not to phase in the fee schedule for providers based on each provider's fiscal year. As described above in section III.C., in general, Medicare's payment per trip to providers is considerably higher than the payment per trip to suppliers. Allowing a phase-in schedule on the provider's fiscal year would provide an advantage for some providers over independent suppliers because the fee schedule would be implemented unevenly across ambulance entities.

Comment: One commenter asked whether the limitation on review (in section 1834(l)(5) of the Act) refers only to the rates established under the ambulance fee schedule.

Response: The limitation on review, by its own terms, prohibits both administrative and judicial review of the amounts established under the fee schedule, including all the "considerations" contained in section 1834(l)(2) of the Act, for example, the definitions for ambulance services and appropriate regional and operational differences. Thus, review of all these issues is precluded.

Revisions and Additions to HCPCS Codes

Claims will be processed using the billing codes created for the ambulance fee schedule and contained in the proposed rule. From these codes, the amount for the portion of the payment based on the current system (80 percent in CY 2002) will be derived using the HCPCS crosswalks as shown below.

We have already changed "old" HCPCS ambulance codes in order to implement the ambulance fee schedule, effective January 1, 2001. The HCPCS codes formerly used to report ambulance services could not be used effective January 1, 2001, except for those HCPCS codes under which a method 3 or method 4 biller may bill for supplies separately (since such billing may continue during the transition period) and those codes previously used to bill for mileage. These codes will be used until the fee schedule is fully implemented.

The following chart shows how the former codes crosswalk to the final new codes under the ambulance fee schedule. Additionally, the chart shows "old" HCPCS codes that will not have a corresponding code under the final ambulance fee schedule. The items and services represented by these codes will be bundled into the base rate services.

Codes Not Valid Under the New Fee Schedule (Codes Terminate Effective 01/01/06): A0382, A0384, A0392, A0396, A0398, A0420, A0422, A0424, A0999.

HCPCS Code Changes:

Current HCPCS Code	New HCPCS Code	Descriptions of final new codes
A0380, A0390	A0425	Ground mileage (per statute mile).
A0306, A0326, A0346, A0366	A0426	Ambulance service, advanced life support, non-emergency transport, level 1 (ALS1).
A0310, A0330, A0350, A0370	A0427	Ambulance service, advanced life support, emergency transport, level 1 (ALS1-Emergency).
A0300, A0304*, A0320, A0324*, A0340, A0344*, A0360, A0364*	A0428	Ambulance service, basic life support, non-emergency transport (BLS).
A0050, A0302, A0308**, A0322, A0328**, A0342, A0348**, A0362, A0368**	A0429	Ambulance service, basic life support, emergency transport (BLS-Emergency).
A0030	A0430	Ambulance service, conventional air services, transport, one way (fixed wing (FW)).
A0040	A0431	Ambulance service, conventional air services, transport, one way (rotary wing (RW)).
Q0186	A0432	Paramedic ALS intercept (PI), rural area, transport

	furnished by a volunteer ambulance company which is prohibited by State law from billing third party payers.
A0433	Advanced life support, Level 2 (ALS2). The administration of at least three different medications and/or the provision of one or more of the following ALS procedures: Manual defibrillation/cardioversion, endotracheal intubation, central venous line, cardiac pacing, chest decompression, surgical airway, intraosseous line.
A0435	Air mileage; fixed wing (per statute mile).
A0436	Air mileage; rotary wing (per statute mile).
A0434	Specialty Care Transport (SCT). In a critically injured or ill beneficiary, a level of inter-facility service provided beyond the scope of the Paramedic. This service is necessary when a beneficiary's condition requires ongoing care that must be provided by one or more health professionals in an appropriate specialty area (for example, nursing, emergency

		medicine, respiratory care, cardiovascular care, or a paramedic with additional training).
	Q3019	Ambulance service, Advanced Life Support (ALS) vehicle used, emergency transport, no ALS level service furnished.
	Q3020	Ambulance service, Advanced Life Support (ALS) vehicle used, non-emergency transport, no ALS level service furnished.

* A new code will be established to indicate during the transition period that where an ALS vehicle was used in a non-emergency situation to furnish only BLS services, the service will be ALS-nonemergency for the old portion of the blended payment and BLS for the Fee Schedule portion of the blended payment.

** A new code will be established to indicate during the transition period that where an ALS vehicle was used in an emergency response and furnished only BLS services, the service will be ALS-Emergency for the old portion of the blended payment and BLS-Emergency for the Fee Schedule portion of the blended payment.

Payment to new suppliers that have not billed Medicare in the past will be subject to the transition period rules. New suppliers will be assigned an allowed charge under the current reasonable charge rules (for new suppliers, the allowed charge is set at the 50th percentile of all charges for the service) and will receive the same blended

transition payments as other ambulance suppliers. In all cases, the transitional payment will be subject (as will the fully implemented fee schedule payment) to the Part B coinsurance and deductible requirements.

Currently, we pay the provider's claims based on the provider's interim rate (the provider's submitted charge multiplied by the provider's past year's cost-to-charge ratio). That interim rate is:

- Cost-settled at the end of the provider's fiscal year, and

- Limited by the statutory inflation factor, contained in section 4531 of the BBA, applied to the provider's allowed cost per ambulance trip from the previous year.

The fee schedule transition will begin on April 1, 2002 and the fee schedule will be phased in on a calendar year basis. Therefore, for providers that file cost reports on a basis other than a calendar year (January 1-December 31) cost-reporting period, for cost-reporting periods beginning after April 1, 2002, two different rates will be blended. Effective for services furnished during 2002, the proposed blended amount for provider claims will equal the sum of 80 percent of the current payment system amount and 20 percent of the ambulance fee schedule amount. Although some providers may receive substantially lower payments than at present, the Committee recommended this particular phase-in, and we believe that our implementing payment under the fee schedule at only 20 percent in the first year will give ambulance providers a period of time to adjust to the new payment amounts. For dates of service in CY 2003, the blended amount will equal the sum of 60 percent of the current payment system amount and 40 percent of the ambulance fee schedule amount. For dates

of service in CY 2004, the blended amount will equal the sum of 40 percent of the current payment system amount and 60 percent of the ambulance fee schedule amount. For dates of service in CY 2005, the blended amount will equal the sum of 20 percent of the current payment system amount and 80 percent of the ambulance fee schedule amount. For dates of service in CY 2006 and beyond, the payment amount will equal the ambulance fee schedule amount. In all cases, the fee schedule portion of the blended rate equals the blending percentage multiplied by the lower of the fee schedule amount or the actual billed charges. The program's payment in all cases will be subject to the Part B coinsurance and deductible requirements.

To assure that providers receive the correct payment amount during the transition period, all submitted charges attributable to ambulance services furnished during a cost-reporting period will be aggregated and treated separately from the submitted charges attributable to all other services furnished in the hospital. Also, providers must maintain statistics necessary for the Provider Statistics and Reimbursement report to ensure that the ambulance fee schedule portion of the blended transition payment will not be cost-settled at cost settlement time.

New providers will not have a cost per trip from the prior year. Therefore, there will be no cost per trip inflation limit applied to new providers in their first year of furnishing ambulance services.

New suppliers will use the CY 2000 allowed charge assigned for new suppliers in accordance with standard program procedures as described above, adjusted for each

year of the transition period by the ambulance inflation factor that we announce.

Section 1834(l) of the Act also requires that all payments made for ambulance services under the proposed fee schedule be made on an assignment-related basis. Pursuant to section 1842(b)(18)(A) and (B) of the Act, incorporated by reference in section 1834(l)(6) of the Act, ambulance suppliers will have to accept the Medicare allowed charge as payment in full and not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts. Violations of this requirement may subject suppliers to sanctions. The law provides that mandatory assignment applies to all services "for which payment is made under" section 1834(l) of the Act; therefore, there will be no transitional period for mandatory assignment of claims. Nor is there any transition to the mechanisms and definitions required by the law. Thus, for instance, the level of services definitions (for example, that claims will be paid for the fee schedule portion of the blended payment at the BLS level if an ALS vehicle was used but no ALS level of service was furnished) will not be subject to transition.

Comment: One commenter stated that we should share the new HCPCS codes with other payers in the interest of consistency among all payers.

Response: HCPCS codes, when established, are routinely shared with all payers.

Comment: A few commenters asked about HCPCS code A0888 (noncovered ambulance mileage) and whether it is being included in the crosswalk of old codes to new ones or is being terminated when the fee schedule is implemented.

Response: HCPCS code A0888 is the code for noncovered ambulance mileage (for example, mileage traveled beyond the closest appropriate facility). This code has not been deleted and may continue to be used as it was previously.

Comment: Some commenters suggested that we maintain current HCPCS codes for ambulance services for use by other payers.

Response: The new codes have been established in accordance with standard procedures that include approval by a national coding committee with representatives from private payers. As a result, HCPCS codes in effect prior to January 1, 2001, for ambulance services have been terminated and replaced by new codes.

Comment: Some commenters asked how payment would be made for new services that did not exist prior to the establishment of the new HCPCS codes (implemented January 1, 2001).

Response: We may determine that a new level of service is necessary to accommodate new expensive technologies. However, the Congress provided only for an inflation factor each year to update the aggregate amount paid under the fee schedule. There is no other provision for increasing the aggregate amount paid for ambulance services in successive years. Therefore, if a new code representing a new level of service is created, the CF would have to be recalculated to preserve this statutory payment limit.

Comment: A few commenters believe that, during the phase-in, suppliers should be allowed to bill for waiting time and an extra attendant.

Response: The phase-in builds upon suppliers' current payments as well as on the fee schedule. Therefore, to the extent that suppliers are currently allowed by their carrier to bill under the reasonable charge system for waiting time and an extra attendant, they may continue to bill in that way during the phase-in only.

Fee Schedule Amounts and Examples of Payment

The table below represents the fee schedule amounts for 2002 under this rule. Note that actual payment rates for 2002 will be a blend of the fee schedule amount and the payment allowances applicable for 2002.

TABLE 1. – 2002 FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES

Service level	RVUs	CF	Unadjusted base rate (UBR) +	Amount adjusted by GPCI (70% of UBR)	Amount not adjusted (30% of UBR)	Loaded mileage	Rural ground mileage (miles 1-17)	Rural ground mileage (miles 18-50)*
BLS	1.00	170.54	$ 170.54	$ 121.65	$ 52.14	$ 5.47	$ 8.21	$ 6.84
BLS-Emergency	1.60	170.54	272.86	191.00	81.86	5.47	8.21	6.84
ALS1	1.20	170.54	204.65	143.26	61.40	5.47	8.21	6.84
ALS1-Emergency	1.90	170.54	324.03	226.82	97.21	5.47	8.21	6.84
ALS2	2.75	170.54	468.99	328.29	140.70	5.47	8.21	6.84
SCT	3.25	170.54	554.26	387.98	166.28	5.47	8.21	6.84
PI	1.75	170.54	298.45	208.91	89.54	(1) No Mileage Rate		

Service level	Unadjusted base rate (UBR)	Amount adjusted by GPCI (50% of UBR)	Amount not adjusted (50% of UBR)	Rural air base rate **	Loaded mileage	Rural air mileage ***
FW	$ 2,314.51	$ 1,157.26	$ 1,157.26	$ 3,471.77	$ 6.57	$ 9.86
RW	2,690.96	1,345.48	1,345.48	4,036.44	17.51	26.27

* A 50 percent add-on to the mileage rate (that is, a rate of $8.21 per mile) for each of the first 17 miles identified as rural. A 25 percent add-on to the mileage rate (that is, a rate of $6.84 per mile) for miles 18 through 50 identified as rural. The regular mileage allowance applies for every mile over 50 miles.

** A 50 percent add-on to the air base rate is applied to air trips identified as rural.

*** A 50 percent add-on to the air mileage rate is applied to every mile identified as rural.

The payment rate for rural air ambulance (rural air mileage rate and rural air base rate) is 50 percent more than the corresponding payment rate for urban services (that is, the sum of the base rate adjusted by the geographic adjustment factor and the mileage).

+ This column illustrates the payment rates without adjustment by the GPCI. The conversion factor (CF) has been inflated for CY 2002.

Legend for Table 1

ALS1 – Advanced Life Support, Level 1

ALS2 – Advanced Life Support, Level 2

BLS – Basic Life Support

CF – Conversion Factor

FW – Fixed Wing

GPCI – Practice Expense Portion of the Geographic Practice Cost Index from the Physician Fee Schedule

PI – Paramedic ALS Intercept

RVUs – Relative Value Units

RW – Rotary Wing

SCT – Specialty Care Transport

UBR – Unadjusted Base Rate

Formulas – The amounts in the above chart are used in the following formulas to determine the fee schedule payments –

Ground

Ground-Urban: Payment Rate = [(RVU*(0.30 + (0.70*GPCI)))*CF] + [MGR*#MILES].

Ground-Rural: Payment Rate = [(RVU*(0.30+(0.70*GPCI)))*CF] + [(((1+RG1)*MGR)*#MILES≤17)+ (((1 + RG2)*MGR)*#MILES18-50) + (MGR*#MILES>50)] (Sign before number 17 was erroneously published in the proposed rule.)

Air

Air-Urban: Payment Rate =
[((UBR*0.50) + ((UBR*0.50)*GPCI))] + [MAR*#MILES].

Air-Rural: Payment Rate =
[(1.00 + RA)*((UBR*0.50)*GPCI))] +
[(1.00+RA)*(MAR*#MILES)].

Legend for Formulas

Symbol and Meaning

≤ = less than or equal to

> = greater than

* = multiply

CF = conversion factor (ground = $159.56; air = 1.0)

GPCI = practice expense portion of the geographic practice cost index from the physician fee schedule

MAR = mileage air rate (fixed wing rate = 6.49, helicopter rate = 17.30)

MGR = mileage ground rate (5.40)

#MILES = number of miles the beneficiary was transported

#MILES<17 = number of miles the beneficiary was transported less than or equal to 17

#MILES18-50 = number of miles beneficiary was transported between 18 and 50

#MILES>50 = number of miles the beneficiary was transported greater than 50

RA = rural air adjustment factor (0.50 on entire claim)

Rate = maximum allowed rate from ambulance fee schedule

RG1 = rural ground adjustment factor amount: first 17 miles (0.50 on first 17 miles)

RG2 = rural ground adjustment factor amount: miles 18 through 50 (0.25 on miles 18 through 50)

RVUs = relative value units (from chart)

UBR = the payment rates without adjustment by the GPCI (unadjusted base rate)

Notes: The GPCI is determined by the address (zip code) of the point of pickup.

Examples Demonstrating Use of Fee Schedule Amounts

The examples in the table and in the discussion below demonstrate the use of the ambulance fee schedule amounts during the first year (2002). Examples 1 through 4 relate to independent supplier claims, and Example 5 relates to hospital-based supplier claims.

TABLE 2. – EXAMPLES DEMONSTRATING USE OF FEE SCHEDULE AMOUNTS

Example	Reasonable charge IIC	Reasonable charge IIC x 80%	2002 fee schedule	2002 fee schedule x 20%	Total allowed charge
1	$ 315.62	$ 252.50	$ 343.66	$ 68.73	$ 321.23
2	292.44	233.95	425.62	85.12	319.07
3	1,982.26	1,585.81	2,987.23	597.45	2,183.26
4	1,564.80	1,251.84	6,250.83	1,250.17	2,502.01
			(Erroneously given in proposed rule in Example 4 as:		
			$ 4,599.69	$ 919.94	$ 2,171.78)

Example 1: Ground Ambulance, Urban (Independent Supplier)

A Medicare beneficiary residing in Baltimore, Maryland, was transported via ground ambulance from his or her home to the nearest appropriate hospital 2 miles away. An emergency response was required, and ALS services, including an ALS assessment, were furnished. Therefore, the level of service is ALS1-Emergency.

Assuming that the beneficiary was placed on board the ambulance in Baltimore, it will be an urban trip. Therefore, no rural payment rate will apply. In Baltimore, the GPCI = 1.038. The fee schedule amount will be calculated as follows –

Payment Rate =
[(RVU*(0.30 + (0.70*GPCI)))*CF] + [MGR*#MILES]

Payment Rate = [(1.90*(0.30 + (0.70*1.038)))*170.54] + [5.47*2.00]

Payment Rate = [(1.90*(0.30 + 0.727))*170.54] + [10.94]

Payment Rate = [(1.90*1.027)*170.54] + [10.94]

Payment Rate = [1.951*170.54] + [10.94]

Payment Rate = [332.724] + [10.94]

Payment Rate = 343.664

Payment Rate = $343.66 (subject to Part B deductible and coinsurance requirements)

Because 2002 will be the first year of a 5-year transition period, the ambulance fee schedule payment rate will be multiplied by 20 percent and added to 80 percent of the payment calculated by the current payment system. The payment rate for Year 2 (CY 2003) will be calculated by

multiplying the ambulance fee schedule payment rate by 40 percent and adding the result to 60 percent of the current payment system amount. The payment rate for Year 3 (CY 2004) will be calculated by multiplying the ambulance fee schedule payment rate by 60 percent and adding the result to 40 percent of the current payment system amount. The payment rate for Year 4 (CY 2005) will be calculated by multiplying the ambulance fee schedule payment rate by 80 percent and adding the result to 20 percent of the current payment system amount. The payment for Year 5 (CY 2006) will be based solely on the ambulance fee schedule.

The applicable codes are A0427 and A0425. Assuming application of the inflation indexed charge (IIC) in 2002, the reasonable charge allowance for this service in Maryland is $315.62 ($303.00 for the base trip plus $6.31 x 2 miles).

Assuming that the Part B deductible has been met, the program will pay 80 percent, and the beneficiary's liability will be 20 percent, representing the Part B coinsurance amount, and the total allowed charge for this service during CY 2002 will be:

Medicare payment (80%)	Beneficiary liability (20%)
$256.98	$64.25

Example 2: Ground Ambulance, Rural (Independent Supplier)

A Medicare beneficiary residing in Cottle County, Texas was transported via ground ambulance from his or her home to the nearest appropriate facility located in Quanah, Texas. Cottle County, where the beneficiary was placed on board the ambulance, is a non-MSA and,

therefore, is, for purposes of this fee schedule, rural. A rural mileage rate will apply. The total distance from the beneficiary's home to the facility is 36 miles. A BLS nonemergency assessment was performed. Under this rule, the level of service will be BLS (nonemergency).

For this part of Texas, the GPCI = 0.880. The proposed ambulance fee schedule amount will be calculated as follows –

36 mile trip = 17 miles at the 50% rural mileage increased rate plus 19 miles at the 25% rural mileage increased rate.

Payment Rate = [(RVU*(0.30 + (0.70*GPCI)))*CF] + [(((1+ RG1)*MGR)*#MILES≤17) + (((1+RG2)*MGR)*# MILES18-50) + (MGR*#MILES>50)]

Payment Rate = [(1.00*(0.30 + (0.70*0.880)))*170.54] + [(((1.00 + 0.50)*5.47)*17.00) + (((1.00 + 0.25)*5.47) *19.00) + (5.47*0.00)]

Payment Rate = [(1.00*(0.30 + 0.616))*170.54] + [((1.50*5.47)*17.00) + ((1.25*5.47)*19.00) + (0.00)]

Payment Rate = [(1.00*0.916)*170.54] + [(8.21*17.00) + (6.84*19.00) + (0.00)]

Payment Rate = [0.916*170.54] + [139.49 + 129.91 + 0.00]

Payment Rate = [156.215] + [269.40]

Payment Rate = 425.615

Payment Rate = $425.62 (subject to Part B deductible and coinsurance requirements)

The total allowed charge for this service during 2002 under our ambulance fee schedule is based on the following codes:

Old HCPCS Code(s) = A0300 and A0380

New HCPCS Code(s) = A0428 and A0425

Assuming application of the inflation indexed charge (IIC) in 2002, the reasonable charge rate for this service in Texas will be $292.44 ($152.76 for HCPCS A0300, $3.88 x 36 miles for A0380).

Assuming that the Part B deductible was met, the program will pay 80 percent, and the beneficiary's liability will be 20 percent, representing the Part B coinsurance amount and the total allowed charge for this service during 2002 will be:

Medicare payment (80%)	Beneficiary liability (20%)
$255.26	$63.81

Example 3: Air Ambulance, Urban (Independent Supplier)

A Medicare beneficiary was involved in an automobile accident along a busy interstate near Detroit, Michigan. A helicopter transported the beneficiary to the nearest appropriate facility located within the city limits of Detroit. The total distance from the accident to the facility was 14 miles. The level of service was rotary wing.

Assuming that the patient was placed on board the air ambulance within the Detroit MSA, and because this is not a Goldsmith county, the trip will be urban. Therefore, no rural payment rate will apply. In the Detroit metropolitan area, the GPCI = 1.038. The ambulance fee schedule amount will be calculated as follows –

Payment Rate = [((UBR*0.50) + ((UBR*0.50)*GPCI))] + [MAR*#MILES]

Payment Rate = [((2690.96*0.50) + ((2690.96*0.50)*1.038))] + [17.51*14.00]

Payment Rate = [(1345.48 + (1345.48*1.038))] + [245.14]

Payment Rate = [(1345.48 + 1396.608)] + [245.14]

Payment Rate = [2742.088] + [245.14]

Payment Rate = 2987.228

Payment Rate = $2,987.23 (subject to Part B deductible and coinsurance requirements)

The total allowed charge for this service during 2002 is based on the following codes:

Old HCPCS Code = A0040

New HCPCS Code = A0431 and A0436

Assuming application of the inflation indexed charge (IIC) in 2002, the reasonable charge rate for this service in Michigan is $1,982.26.

Assuming that the Part B deductible has been met, the program will pay 80 percent, and the beneficiary's liability will be 20 percent, representing the Part B coinsurance amount; and the total allowed charge for this service during 2002 will be:

Medicare payment (80%)	Beneficiary liability (20%)
$1,746.61	$436.65

Example 4: Air Ambulance, Rural (Independent Supplier)

A Medicare beneficiary was transported via helicopter from a rural county in Arizona to the nearest appropriate facility. The total distance from point of pick-up to the facility was 86 miles. The level of service was rotary wing.

Because the point of pick-up was in a rural, non-MSA area, this transport will be a rural trip under this rule. Therefore, a rural payment rate will apply. In Arizona, the GPCI = 0.978. The ambulance fee schedule amount will be calculated as follows –

Payment Rate = [(1.00+RA)*((UBR*0.50) + ((UBR*0.50) *GPCI))] + [(1.00+RA)*(MAR*#MILES)]

Payment Rate = [(1.00+0.50)*((2690.96*0.50) + ((2690.96 *0.50)*0.978))] + [(1.00+0.50)*(17.51.*8600)]

Payment Rate = [(1.50)*(1345.48 + (1345.48*0.978))] + [1.50 *1505.86]

Payment Rate = [(1.50)*(1345.48 + 1315.879)] + [2258.79]

Payment Rate = [1.50*2661.359] + [2258.79]

Payment Rate = [3992.039] + [2258.79]

Payment Rate = 6250.829

Payment Rate = $6,250.83 (subject to Part B deductible and coinsurance requirements)

The total allowed charge for this service during 2002 is based on the following codes:

Old HCPCS Code = A0040

New HCPCS Code = A0431 and A0436

Assuming application of the inflation indexed charge (IIC) for the example in question, in 2002 the reasonable charge rate for this service in Arizona will be $1,564.80.

Assuming that the Part B deductible has been met, the program will pay 80 percent and 20 percent will be the beneficiary's liability and the total allowed charge for this service during 2002 will be:

Medicare payment (80%)	Beneficiary liability (20%)
$2,001.61	$500.40

(These figures were erroneously given in the proposed rule as:

Medicare payment (80%)	Beneficiary liability (20%)
$1,737.42	$434.36)

Example 5: Ground Ambulance, Rural (Hospital-Based Supplier)

A Medicare beneficiary residing in a rural area in the state of Iowa was transported via ground ambulance from her home located in a rural area (non-MSA) to the nearest appropriate facility (Hospital A). Because the point of pick-up is in a rural area, under our final rule, a rural payment rate will apply. The total distance from the beneficiary's home to Hospital A is 14 miles. A BLS nonemergency transport was furnished. The level of service will be BLS (nonemergency).

For Iowa, the GPCI = 0.876. The ambulance fee schedule amount will be calculated as follows –

14 mile trip = 14 miles at the rural mileage rate plus 0 miles at the regular urban rate.

The HCPCS codes to be used under the fee schedule are A0428 and A0425.

Payment Rate = [(RVU*(0.30 + (0.70*GPCI)))*CF] + [(((1 + RG1)*MGR)*#MILES≤17) + (((1 + RG2)*MGR)* # MILES18-50) + (MGR*#MILES>50)]

Payment Rate = [(1.00*(0.30 + (0.70*0.876)))*170.54] + [(((1.00 + 0.50)*5.47)*14.00) + (((1.00+0.25)*5.47)*0.00) + (5.47*0.00)]

Payment Rate = [(1.00*(0.30 + 0.613))*170.54] + [((1.50 *5.47)*14.00) + ((1.25*5.47)*0.00) + (0.00)]

Payment Rate = [(1.00*0.913)*170.54] + [(8.205*14.00) + (6.838*0.00) + (0.00)]

Payment Rate = [0.913*170.54] + [114.87 + 0.00 + 0.00]

Payment Rate = [155.703] + [114.87]

Payment Rate = 270.573

Payment Rate = $270.57 (subject to Part B deductible and coinsurance requirements)

Since 2002 will be the first year of a 5-year transition period, the ambulance fee schedule payment rate will be multiplied by 20 percent. The portion of the total payment under the final fee schedule for 2002 is:

Payment Rate = Fee Schedule * Transition Percentage

Payment Rate = 270.57*0.2

Payment Rate = 54.114

Payment Rate = $54.11

The remaining 80 percent of the payment rate is determined by the current payment system. For FIs, the current payment calculation is as follows.

Assume that Hospital A's charge (HCB) for a BLS-nonemergency service is $220.00, its charge for mileage (HCM) is $4.00 per mile, and its past year's cost-to-charge ratio (CCR) is 0.9.

Assuming that the beneficiary's Medicare Part B deductible has been met, the beneficiary's coinsurance liability for 2002 will be $55.10, calculated as follows:

Total Charge = HCB + (HCM*#MILES)

Total Charge = 220.00 + (4*14)

Total Charge = 220.00 + 56

Total Charge = $276.00 (Current system)

For 2002, the coinsurance is equal to 20 percent of:

Total rate = (0.80*Current System) + (0.20*FS)

Total rate = (0.80*276.00) + (54.71)

Total rate = (220.80) + (54.71)

Total rate = $275.51

Coinsurance = 0.20*275.51 = $55.10

For 2002, the transition payment rate is equal to:

Transition payment rate = [0.80*current rate] + [0.20*FS]

Transition Payment Rate = [0.80*((HCB)+(HCM* #MILES))*CCR]+[0.20*FS]

Transition Payment Rate = [0.80*((220.00) + (4*14))*0.9] + [54.11]

Transition Payment Rate = [0.80*((220.00)+(56))*0.9] + [54.11]

Transition Payment Rate = [0.80*(276.00)*0.9] + [54.11]

Transition Payment Rate = [198.72] + [54.11]

Transition Payment Rate = $252.83

Assuming the part B deductible is met:

Medicare program payment = (transition payment rate)-(coinsurance)

Medicare program payment = 252.83 – 55.10

Medicare program payment = $197.73

V. Mechanisms To Control Expenditures for Ambulance Services

We do not anticipate that the number of ambulance services furnished will increase to offset the effects of lower payments per service, and the Committee did not suggest mechanisms to control expenditures. However, we will monitor payment data and evaluate whether our assumptions used to calculate the original CF (for example, the ratio of the volume of BLS services to ALS services or the number of low billers) are accurate. If the actual proportions of the various levels of service are different (higher or lower) than those projected, we will adjust the CF accordingly.

VI. Adjustments To Account for Inflation and Other Factors

In setting the CF for CY 2002, we are adjusting the base year data from 1998 for inflation. Section 4531 of the Balanced Budget Act of 1997, as amended by section 423 of BIPA, prescribes the inflation factor to be used in determining the payment allowances for ambulance services paid under the current Medicare payment system. The inflation factor is equal to the projected consumer price index for all urban consumers (U.S. city average) (CPI-U) minus 1 percentage point from March-to-March for claims paid under cost payment (providers) and from June-to-June for claims paid under the reasonable charge system (carrier processed claims). The base year for our data is 1998. The inflation factors as percents are:

	March-to-March (provider claims) (percentage)	June-to-June (carrier claims) (percentage)
1999/1998	0.9	1.1
2000/1999	2.4	2.0
2001/2000*.....	3.7	3.7
2002/2001	2.2	2.2
Compounded inflation factor* (DOS = 1/1/02-12/31/02)	9.50	9.29

* For date of service (DOS) during the 6-month period 1/1/01-6/30/01, the inflation factor was 2.7 percent, and for the 6-month period 7/1/01-12/31/01, the statutory inflation factor is 4.7 percent for an average of 3.7 percent for 2001.

In addition, the Committee acknowledged that the statutory provisions in section 1834(l)(3)(B) of the Act, regarding annual updates to the fee schedule, will be used to make adjustments to account for inflation. That section of the Act provides for an annual update to the ambulance fee schedule based on the percentage increase in the CPI-U for the 12-month period ending with June of the previous year. Section 4531 of the BBA provided that, for 2001 and 2002, the increase in the CPI-U would be reduced by 1.0 percentage point for each year. However, this section was amended by BIPA, which mandated that the inflation factor for the period July 1, 2001 through December 31, 2001 be 4.7 percent.

As we indicated in the proposed rule, we will monitor payment data and evaluate whether certain assumptions used to establish the original CF (for example, the ratio of the volume of BLS services to ALS services) are accurate. Where appropriate, we will adjust the CF accordingly.

In addition, we note that the inflation factor also applies to all mileage rates.

Comment: Some commenters stated that the inflation factor referred to in the proposed rule is not correct for the year 2001. They stated that it should be the change in the CPI-U over the one-year period ending with June 30, 2000, minus one percent. The commenters recommended that, since the statutory inflation factor for 2001 is the CPI-U increase for the 12-month period ending in June of the previous year, we should be using that factor for the 2001 update, rather than an estimate for the 12-month period ending in June of 2001.

Response: We agree. However, the Congress has since enacted a change in the ambulance inflation factor for part of 2001. Section 423 of BIPA provides that this factor be increased to 4.7 percent for the period July 1, 2001 through December 31, 2001.

Comment: Some commenters requested that we limit any adjustments to the CF to include only adjustments for the factors mentioned in the preamble. They state, for example, that the industry has no control over total volume of services and believe that we should not reduce the CF to offset increased charges resulting from any possible increase in total ambulance trips.

Response: We are not reducing the CF to offset increased program payments that result from an increase in the total volume of ambulance trips.

Comment: One commenter stated that operational costs in California (for example, personnel, insurance, fuel) are higher than other areas and the fee schedule should recognize these higher costs.

Response: Differences in operational costs due to location are reflected in the fee schedule through the GPCI. This index is derived from cost-of-living factors in the operation of a physician's office, such as personnel, insurance, electricity. The Committee believed that this index was the most appropriate of the indices available to use for the ambulance fee schedule.

VII. Medical Conditions Lists

When the Congress mandated that the ambulance fee schedule be developed through the negotiated rulemaking process, we deferred final action on our earlier proposal to base Medicare payment on the level of ambulance service required to treat the beneficiary's condition. The proposed ambulance coverage rule, published on June 17, 1997 (62 FR 32715), also included diagnostic codes based on the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) that would have described the nature of the beneficiary's medical condition. Use of the ICD-9-CM codes would have assisted ambulance suppliers in billing the medically necessary level of ambulance service.

While we did not propose a medical conditions list in the September 2000 proposed rule (65 FR 55078), and while a medical conditions list, or codes for such a list, were not an official part of the negotiated rulemaking process, some of the negotiated rulemaking participants and other medical professionals, including carrier medical directors, emergency room physicians, and the Emergency Nurses Association, came together as an ad hoc workgroup to discuss this issue. Their aim was to develop a list of medical conditions, not diagnoses, that generally require

ambulance services and to identify the appropriate level of care for these conditions. The identified condition(s) would describe the beneficiary's medical condition, as presented to the ambulance crew upon arrival on the scene. The workgroup's final report was submitted to the Committee as a recommendation for further consideration.

We published the list of medical conditions as Addendum A in the September 12, 2000 proposed rule (66 FR 55096). Suppliers and providers may submit these conditions on their Medicare claims. If they choose to do so, the condition must be reported in the "remarks" field on the claim. We will instruct Medicare contractors that they may not deny or reject claims solely because a supplier or provider has reported on the claim one of the conditions from the list of conditions. Also, the presence of a condition, in and of itself, does not establish the ambulance service as reasonable and necessary. Regardless of the presence of the condition on the claim, ambulance suppliers and providers must maintain and, upon request by the Medicare contractor, submit documentation sufficient to show that the service was reasonable and necessary. In other words, the presence of an identified condition on the claim will not make the claim payable if the beneficiary could have been safely transported by other means.

We noted in the proposed rule that we have solicited information from interested parties on the need for such a list and the development of codes used in association with such a list that would best support the processing of claims for ambulance services. We also noted that, while we were not requiring the use of the conditions list at that time, we intended to work with members of the industry and other affected parties to develop a more complete set of conditions as well as a coding system that could be used

under the fee schedule. Any such coding system, after August 16, 2002, would have to be created consistent with the electronic claim standards developed pursuant to the Health Insurance Portability and Accountability Act of 1996, Public Law 104-91 (HIPAA), described in the Federal Register on August 17, 2000 (65 FR 50311).

Comment: The majority of the comments on this subject stated that the list of condition descriptions should be adopted as written. Some commenters recommended that we not implement the fee schedule until we can implement the medical conditions list. The commenters stated that a coding system, upon which the new fee schedule is based, should include a means for suppliers and providers to indicate on the claim the symptoms presented by the beneficiary to the ambulance crew at the time of arrival on the scene that justify the level of service they furnish.

Commenters also expressed concern that the medical conditions list is necessary for providers and suppliers to be able to report the appropriate level of service. One commenter noted that implementing the fee schedule without the medical conditions list will cause great hardship and confusion for ambulance suppliers and carriers regarding billing and claims processing.

Response: The ambulance fee schedule is based upon HCPCS codes that reflect the level of services provided to the beneficiary. We have set forth in this final rule the seven levels of service upon which payment for ground ambulance services will be based. Although the medical conditions may be used as a guide to indicate the appropriate level of ground ambulance service, they are not necessary in order to proceed with the implementation of

the fee schedule. The ambulance fee schedule, which is simply a pricing mechanism, does not depend upon the use of a coding system denoting the list of conditions.

Under the current billing rules for ambulance services, Medicare carriers may request that suppliers document that the trip was medically necessary and that the appropriate level of service was provided. Currently, suppliers provide this documentation by using – (a) an explanation on the claims forms, (b) ICD-9-CM diagnosis codes, and/or (c) medical records.

As we stated above and in the proposed rule, we agree that a medical conditions list would help the ambulance supplier to identify the level of service at which a claim may be paid and would also aid Medicare contractors in their efforts to ensure that claims for ambulance services are paid appropriately. We understand the importance of implementing a uniform set of condition codes that all providers and suppliers can use. While this regulation does not contain such a set of codes, we pledge to work with the ambulance providers and suppliers, including hospitals, to develop a uniform set of codes over the next year. If a provider or supplier wishes to use the existing set of ICD-9-CM diagnosis codes, we will instruct our carriers and intermediaries to review that set of codes.

However, when the issue of a list of medical conditions was raised in the Committee, we advised the Committee that, while defining the levels of ambulance service was within the scope of the Committee, establishing the medical conditions that justify those levels of payment was not within that scope. Furthermore, we advised that recommendations about a coding system would have to be consistent with the regulations published pursuant to

HIPAA. The HIPAA standards for electronic transactions final rule (65 FR 50312), which was published on August 17, 2000, established, among other things, Standards for the health care claims or equivalent encounter information transaction (45 CFR 162.1102). In general, the standards for that transaction require a specific format, the ASC X12N 837, and specify the use of certain medical data code sets when the transaction is transmitted electronically by an entity subject to the rule. Under HIPAA, the ASC X12N 837 and the specified code sets for the health care claims transactions do not currently support the use of condition descriptions lists. However, HIPAA provides for the maintenance and modification of adopted standards and for the adoption of new standards, as set forth in the regulations at § 162.910. Therefore, it is possible that, in the future, the health claims standards could be modified or expanded, or new standards created, in accordance with the procedures set forth in regulations, to accommodate condition descriptions lists.

Comment: Commenters did not agree on the appropriate coding system to be used for the conditions list. Some commenters believe that ICD-9 or ICD-10 codes should be associated with the condition descriptions, while others believe that we should not specify ICD-9 or ICD-10 codes as an appropriate system to determine medical conditions. Still others suggested that most conditions in the list could be mapped to existing ICD-9-CM codes, and the remaining conditions could be mapped to HCPCS codes. This approach would avoid the large expense to providers of implementing another coding system.

Response: As noted above, there are many factors to be considered before we make a final decision regarding

the development of an ambulance-specific medical condition coding system. We also note that the example in the proposed rule mistakenly referenced ICD-10-CM codes and should have referenced ICD-9-CM codes.

Comment: One commenter stated that we should require Medicaid to use the new medical condition codes.

Response: States are not obligated to adopt Medicare guidelines for ambulance services.

IX. Provisions of the Final Rule

A. BIPA

BIPA provides the following changes to the ambulance fee schedule that have been incorporated into this rule.

• Critical Access Hospital (CAH) – The proposed rule would apply the ambulance fee schedule to all entities furnishing ambulance services to Medicare beneficiaries. Section 205 of BIPA provides that CAHs, or entities owned and operated by them, are paid for ambulance services based on reasonable cost, if there is no other ambulance provider or supplier within a 35-mile drive. As a result, these entities are exempt from the ambulance fee schedule described in this final rule. These entities are also exempt from the current cost-per-trip inflation cap applicable to providers. This cap, established by section 4531(a)(1) of the BBA, limits increases in the cost per trip of ambulance services from each year to the next by the consumer price index for all urban consumers, reduced by 1 percentage point. Implementation of section 205 of BIPA requires us to establish a process for a CAH to qualify for this exemption. Such a process was addressed in a separate final rule, "Medicare

Program; Changes to the Hospital Inpatient Prospective Payment Systems and Rates and Costs of Graduate Medical Education; Fiscal Year 2002 Rates, etc.; Final Rules," published August 1, 2001 (66 FR 39828). The payment policy component is addressed in this rule.

• Rural Ambulance Mileage – The proposed rule would pay rural mileage greater than 17 at the same rate as mileage within urban areas. Section 221 of BIPA provided that the payment rate for rural ambulance mileage greater than 17 miles and up to 50 miles be increased by not less than one-half of the additional payment per mile established for the first 17 miles of a rural ambulance trip. We are waiving proposed rulemaking for this provision because we believe this amount is the minimum that is required by the plain language of the law and is not discretionary. We believe that proposed rulemaking, which would be necessary to set the amount at a level higher than the minimum, is impracticable in this instance for timely implementation of the law and will therefore implement it as a final with comment. Therefore, we will accept public comments on this policy.

• Inflation Factor – The proposed rule would increase the per trip payments for services furnished in 2001 over the per trip payments for these services furnished in 2000 by an amount equal to the change in the CPI-U reduced by one percent. Section 423 of BIPA provided that the ambulance inflation factor for services furnished during the period July 1, 2001 through December 31, 2001 be equal to 4.7 percent. We have implemented this provision without proposed rulemaking because it was self-implementing and neither permitted nor required interpretation.

• Ground Ambulance Mileage – The proposed rule would pay for all ground ambulance mileage during a four-year transition period based on a blend of the current payment rate and the fee schedule rate. Section 423 of BIPA also provided that all mileage furnished by suppliers and paid by carriers would be paid at the full fee schedule amount without any phased-in blended payment, but only in those States in which, prior to the fee schedule, the carrier paid separately for all mileage outside the county from which the beneficiary was transported, but did not pay separately for any in-county ambulance mileage. This provision does not apply to providers. We are waiving proposed rulemaking for this provision because we believe this amount is the minimum that is required by the plain language of the law and is not discretionary. We believe that proposed rulemaking is impracticable in this instance for implementation of the law and will therefore implement it as a final with comment. Therefore, we will accept public comments on this policy.

B. Inflation

First, we corrected the inflation factor for 2001 to be equal to the percentage increase in the CPI-U minus one percent for the 12-month period ending in June of the previous year. This factor is applied to services furnished in the period January 1, 2002 through December 31, 2002.

Second, we clarify that the ambulance inflation factor applies to all mileage rates.

C. Physician Certification

We added a provision which states that the health care professional who may certify the necessity of an

unscheduled non-emergency ambulance transport may be an employee of the attending physician. Previously, we had required this person to be an employee of the facility in which the beneficiary was receiving treatment. We also clarified that all of the Medicare regulatory requirements and State licensure requirements for these health care professionals apply.

We changed the requirement for certification for non-repetitive scheduled non-emergency ambulance transports. These transports no longer require certification in advance. They are now treated the same as unscheduled non-emergency ambulance transports for certification purposes. Certification in advance is now required only for repetitive scheduled non-emergency ambulance transports.

In addition, we added the words "provider or" to clarify that the same certification requirements apply to both providers and suppliers.

D. Bed-Confined

We clarified that bed-confinement is not necessarily sufficient justification for the medical necessity of a non-emergency ambulance transport. Other documentation may also be required. Other conditions in beneficiaries who are not bed-confined may also justify the medical necessity of a non-emergency transport by ambulance.

E. Future Adjustments to the Conversion Factor

We clarified the factors for which we will adjust the CF. We will not, for example, adjust the CF in response to an increase in the total number of ambulance transports

over the number of transports in the previous year. We will adjust the CF if actual experience under the fee schedule is significantly different from the assumptions used to calculate the CF (for example, the relative volumes of the different levels of service or the extent of charges below the fee schedule (that is, "low billers")).

F. Adjustment for "Low Billing"

We have decided to assume that one-half of these "low billers" (that is, those billers whose charge is less than 70 percent of the maximum allowed by Medicare) would continue to charge an amount that is lower than the fee schedule amount. Therefore, we have increased the CF to account for approximately $42 million that we anticipated as the difference between the aggregate fee schedule amount and actual charges that will be significantly less than the fee schedule amount (that is, "low billing").

G. Ambulance Blueprint

We changed the criteria in the definitions of the services that constitute a BLS level and an ALS level of care from those in the national Blueprint to the criteria contained in State and local laws.

H. ALS Assessment

We changed the definition of ALS assessment to conform to the definition in the Committee Statement and to clarify that an ALS assessment is recognized only in an emergency situation.

I. Emergency Response Definition

In the proposed rule, we stated that an emergency response means responding immediately to an emergency medical condition. An immediate response is one in which the ambulance supplier begins as quickly as possible to take the steps necessary to respond to a call. We deleted the phrase "emergency medical condition" from the definition of "emergency response." We clarified that the additional payment for emergency response is for the additional overhead cost of maintaining the resources required to respond immediately to a call and not for the cost of furnishing a certain level of service to the beneficiary. We also clarified that "emergency response" refers only to a BLS or ALS1 level of service.

J. Delayed Implementation

We will implement the fee schedule on April 1, 2002. The proposed rule had stated implementation would be January 1, 2001.

K. Drug Administration Which Supports an ALS2 Level of Services

We clarified the types of drugs that must be administered to the beneficiary in order for the ambulance transport during which the administration occurs to qualify for payment at the ALS2 level. We also clarified that three separate administrations of the same drug qualifies for the ALS2 level of care.

L. Multiple Patients

We changed the amount paid for transports in which there is more than one patient onboard the ambulance. In the proposed rule, we stated that a single transport fee would be allowed and distributed equally among the patients. In this final rule, we provide that payment will be made as follows. If two patients are transported simultaneously, for each Medicare beneficiary, we will allow 75 percent of the payment allowance for the base rate applicable to the level of care furnished to that beneficiary. If three or more patients are transported simultaneously, then the payment allowance for the Medicare beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary. However, a single payment allowance for mileage would continue to be prorated by the number of patients onboard.

M. Changes to the Conversion Factor

Several changes have been made to the calculation of the CF from the methodology described in the proposed rule. The inflation factor used for calendar year 2001 was set at 3.7 percent. This is the annualized inflation factor provided by BIPA which has the effect of an inflation factor of 2.7 percent for the period January 1, 2001 through June 30, 2001, and 4.7 percent for the period July 1, 2001 through December 31, 2001 (as described above). Second, the CF was increased to reflect the assumption that some "low billers" (as described above) will continue to submit charges less than the fee schedule amount. Third, we corrected the number of rural miles equal to or less than 17 miles that were billed in calendar year 1998. Fourth, we revised our assumption with respect to the

number of services that we believe will be billed at the ALS1-Emergency level because a supplier that provides an "ALS assessment" may receive payment for an ALS1-Emergency level of service. Fifth, we added back to the total amount used to calculate the CF the savings that would have accrued to the program had we implemented the policy proposed in June 1997 that would pay at the BLS rate for services furnished at the BLS level even though an ALS vehicle was used.

N. Deceased Beneficiary

We have clarified that, in the case of an air ambulance responding to a call for a beneficiary who was pronounced dead while the ambulance was enroute to the scene, payment will be made in the amount of the appropriate air base rate and not in the amount of a BLS ground rate. No payment will be made for mileage.

O. Medical Conditions List

We have specified that suppliers and providers may choose to submit a condition from the list of conditions and, if they do submit a condition, they must report that condition in the "remarks" field on the claim. Contractors may not deny or reject claims solely because a supplier or provider has reported a condition on the claim. Also, the presence of a condition, in and of itself, does not establish whether the services were reasonable and necessary. Regardless of the presence of the condition on the claim, ambulance suppliers and providers must maintain and, upon request by the Medicare contractor, submit documentation sufficient to show that the service was reasonable and necessary.

P. Transition Period

The transition period has been changed from the four-year transition in the proposed rule. The final rule provides a five-year transition with blended payments as follows:

	Former payment percentage	Fee schedule percentage
Year One (4/2002-12/2002)	80	20
Year Two (CY 2003)	60	40
Year Three (CY 2004)	40	60
Year Four (CY 2005)	20	80
Year Five (CY 2006)	0	100

Q. Payment for BLS Services Furnished by ALS Vehicle During Transition Period

In the proposed rule, we stated that during the transition period the "old" portion of the blended payment for BLS services furnished using an ALS vehicle would be the payment allowance for a BLS trip. In the final rule, we are phasing in this policy and the "old" portion of the blended payment will be at the allowance for an ALS trip.

X. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment when a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of

the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

Coverage of Ambulance Services (§ 410.40(d)(2))

This section is revised so that it no longer requires that an ambulance provider or supplier, before furnishing nonemergency, scheduled, nonrepetitive services to a beneficiary obtain a written order from the beneficiary's attending physician certifying that the services are medically necessary prior to the date the service is furnished.

Coverage of Ambulance Services (§ 410.40(d)(3)(iii))

This section states that if the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a signed certification statement must be obtained from either the physician assistant (PA), nurse practitioner

(NP), clinical nurse specialist (CNS), registered nurse (RN), or discharge planner, who has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished. This individual must be employed by the beneficiary's attending physician, or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported. Medicare regulations for PAs, NPs, and CNSs apply and all applicable State licensure laws apply.

The burden associated with this requirement is the time and effort necessary for the required hospital or physician's employee to provide the certification. We estimate that there will be approximately 5,000 certifications on an annual basis at an estimated 5 minutes per certification. Therefore, the annual national burden associated with this requirement is 417 hours.

Coverage of Ambulance Services (§ 410.40(d)(3)(iv) & (v))

The following paragraphs also have information collection requirements:

Paragraph (d)(3)(iv): If the ambulance provider or supplier is unable to obtain the required certification within 21 calendar days following the date of the service, the ambulance provider or supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance provider or supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (d)(3)(iii) above.

Paragraph (d)(3)(v): In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the signed certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

The burden associated with these requirements is the time and effort necessary for the ambulance provider or supplier to document its attempts to obtain the requested certification statement and the time and effort necessary for the hospital or physician's employee to document the certification statement itself. We estimate that 5,000 providers or suppliers will be required to submit a receipt instead of certification for an average of 12 instances each on an annual basis, at an estimated 5 minutes per instance for a total annual national burden of 5,000 hours. We also estimate that there will be 5,000 certifications to be documented by the hospital or physician's employee at 5 minutes per instance for a total annual national burden of 417 hours.

Point of Pick-Up (§ 414.610(e))

This section states that the zip code of the point of pick-up must be reported on each claim for ambulance services so that the correct GAF and RAF may be applied, as appropriate.

In the proposed rule, we stated that the burden associated with this requirement is the time and effort necessary for the ambulance provider or supplier to note the required zip code for each claim of service. We estimated that, of the 9,000 (potential) providers or suppliers,

5,000 providers or suppliers will be required to provide the documentation, for an estimated 550,000 (5% of total claims volume of 11 million) instances on an annual basis. Per provider or supplier (5,000), we estimate 1 minute per instance to meet this requirement, for a burden of 2 hours per provider or supplier on an annual basis. Therefore, the annual national burden associated with this requirement is 10,000 hours.

Comment: A few commenters stated that the burden of reporting the zip code on the claim applies to 100 percent of total volume of claims and more than 2 hours per supplier per year.

Response: We agree with the commenters. The burden of reporting the zip code applies to all claims for ambulance services and to all providers and suppliers. We estimate that there will be approximately 10 million claims for ambulance services, from approximately 10,000 ambulance providers and suppliers, each of which will require the zip code to be entered. We estimate that entering the zip code requires about 15 seconds, giving a total annual burden of approximately 40,000 hours or an average of 4 hours per provider or supplier per year. We expect that this burden will diminish as providers and suppliers become familiar with the zip codes in their service area.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn.: Dawn Willinghan

(Attn: CMS-1002-om N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850;

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, CMS Desk Officer.

XI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This final regulation will have no fiscal impact on the Medicare program; therefore, we have determined that this is not a major rule. However, we are providing a regulatory impact analysis because some entities will experience a decrease in payments while others will experience an increase in payments. This impact is less than the $70 million savings estimate for FY 2002 shown in the proposed rule because we are paying for BLS services furnished by ALS vehicles at the ALS rate for the reasonable charge portion of the blended rate during the transition period and because we have increased the amount of spending upon which the CF is based by the

amount paid for ALS vehicles that furnished only a BLS level of service. In addition, our data indicate that payments (80 percent of which will be program expenditures and the remainder because of Medicare Part B coinsurance and deductible requirements) will be redistributed among entities that furnish ambulance services.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. For purposes of the RFA, most ambulance providers and most ambulance suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. In the aggregate, in 2002, rural entities, which include both rural hospitals and rural ambulance suppliers, will receive an increase in total revenue while urban entities will experience a decrease in total revenue as summarized in the chart, below. It is also true that some rural entities will be paid less than their current rate. While we do not have specific data on the number of small rural hospitals that furnish ambulance services, we recognize that the rural adjustment factor incorporated in this proposal may not completely offset the

higher costs of low-volume suppliers. As stated earlier, we recognize that this rural adjustment is a temporary proxy to acknowledge the higher costs of certain low-volume isolated and essential suppliers. We will consider alternative methodologies that would more appropriately address payment to isolated, low-volume rural ambulance suppliers. In addition, critical access hospitals that do not have an ambulance supplier within a 35-mile drive will be paid for ambulance services based on cost.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. The final rule will not have any unfunded mandates.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. The final rule will not impose compliance costs on the governments mentioned.

Although we view the anticipated results of this final regulation as beneficial to the Medicare program and to Medicare beneficiaries, we recognize that not all of the potential effects of this final rule can be anticipated.

The foregoing analysis concludes that this regulation may have a financial impact on a number of small entities. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by the RFA.

Comment: Many commenters noted that this is a major rule and that we should conduct a regulatory impact analysis under Executive Order 12866. They argue that the impact is more than $84.5 million because it should include: (1) The effects of our treatment in calculating the conversion factor of suppliers with low charges and those that do not bill for mileage; (2) redistribution effects; and (3) the effect of mandatory assignment of benefits. In addition, the rule does not discuss the impact on public safety of the ambulance suppliers who will experience a reduction in payments. The commenters noted that we should conduct a State-by-State impact assessment of the proposed rule to determine if there are regulatory alternatives that would have a less drastic effect on ambulance providers, many of whom are small businesses.

Response: As stated above, we have determined that this is not a major rule and that this final rule has no fiscal impact on the program. With respect to the mandatory assignment requirement, historically, ninety-five percent of ambulance services have been submitted to Medicare under assignment, and, while the fee schedule redistributes payments, we do not anticipate that the assignment requirement will be a major issue nationally. There may be areas of the country where balanced billing occurs more often than in other parts; however, the effect on total payments is unclear because payment in any of the areas may increase under the fee schedule. Also, as stated above, mandatory assignment of benefits is a requirement of the law and not subject to the discretion of the Secretary through this regulatory action. Also, we have included an amount in this final rule for suppliers of ambulance services who may choose not to bill the program at the full fee schedule amount.

B. Anticipated Effects

Implementation of the ambulance fee schedule will have several general effects. Section 1834(l)(3)(A) of the Act requires that the aggregate amount paid under the ambulance fee schedule not exceed the aggregate amount that would have been paid absent the fee schedule. One of the characteristics of the present payment system is that widely varying amounts are paid for the same type of service depending upon the location of the service. In effect, the ambulance fee schedule will lower payments in areas of high current levels of payment and raise payments in areas of low current levels of payment. Thus, a given area could have a large reduction in payment only because such an area had historically been paid at a rate higher than average for the type of service. Even with a reduction, such an area may continue to have payment rates under the fee schedule that are higher than the national average.

1. Effect on Ambulance Providers and Suppliers

One effect of the fee schedule will be that revenue will be redistributed from providers to ambulance suppliers because providers have been paid, on average, more for the same service furnished by a supplier.

2. Effects on Urban, Rural, and Air Ambulance Services

Payment could be redistributed from urban ambulance services to rural ambulance services for two reasons:

(1) Services furnished in urban areas have been paid more, on average, than the same services furnished in rural areas.

(2) The ambulance fee schedule will pay more for the same services furnished in a rural area than in an urban area because of the rural adjustment factor (RAF). Payment will also be redistributed from urban air ambulance services to rural air ambulance services because of the RAF for air services.

(3) Finally, there will be a redistribution of payment from ground ambulance services to air ambulance services. This effect is explained in greater detail in the discussion of the CF.

Currently, providers (for example, hospital-based ambulance services) are paid on average 66 percent more than independent suppliers for the same type of ambulance service. This is because providers are currently paid based on reasonable cost and suppliers are paid based on reasonable charges capped by the inflation indexed charge (IIC). The IIC has limited the growth of suppliers' payments over the years, whereas, until enactment of the BBA in 1997, there had not been a limit on the growth of providers' reimbursable cost for ambulance services. As a result, providers of ambulance services will experience a reduction in total revenue while independent ambulance suppliers will experience an increase in total revenue.

There are offsetting factors that affect payment in urban versus rural areas. While payment rates in rural areas will generally be lowered by the GPCI (because the GPCI is generally lower in rural areas than it is in urban areas), rural payment rates will increase because of the rural mileage add-on. The net result is that payments will be redistributed from providers and suppliers in urban areas to providers and suppliers in rural areas.

Furthermore, payments will be redistributed from providers and suppliers of ground ambulance services to providers and suppliers of air ambulance services.

The following chart summarizes these findings for 2002:

From	To	Revenue (million)
Providers	Suppliers	$14
Urban.....	Rural.....	17
Ground.....	Air.....	5

These amounts represent total revenue, that is, the 80 percent Medicare portion plus the 20 percent beneficiary coinsurance liability. The redistributive effects of this final rule represent a negligible fraction of the total revenue (both Medicare at $2.7 billion plus all other non-Medicare sources of revenue) for ambulance providers and suppliers. Therefore, we conclude and the Secretary certifies that this final rule does not have a significant impact on a substantial number of small entities.

3. Effect on the Medicare Program

We estimate that this final rule will have no fiscal impact on the Medicare program.

C. Alternatives Considered

While there were many alternatives considered during the course of the negotiated rulemaking process, the statute requires that total program expenditures not exceed what the payments would have been without the fee schedule. None of the alternatives considered changed total program expenditures. The alternatives varied in the

manner in which the total amount of program expenditures might be distributed among the entities that furnish ambulance services to Medicare beneficiaries. For example, the Committee considered other geographical adjustment factors, other relative values for the levels of ambulance service, other definitions for the levels of ambulance service and other definitions for "rural entities," but it did not adopt them for various reasons. (A full description of these alternatives may be found at the Web site: www.hcfa.gov/medicare/ambmain.htm.)

D. Effect on Beneficiaries

The ambulance fee schedule will have a leveling effect on coinsurance liability. About 10 percent of the 37 million beneficiaries enrolled in Medicare Part B receive a Medicare benefit for ambulance services. While beneficiaries in those areas of historically higher than average payment rates will benefit from lower coinsurance liability, beneficiaries in areas of historically lower than average payment rates will experience an upward trend of coinsurance liability. While, on average, for all Medicare beneficiaries receiving a Medicare benefit for ambulance services there is no change in coinsurance liability, the average beneficiary coinsurance liability will increase by one percent for beneficiaries located in rural areas with the same decrease in coinsurance liability for beneficiaries in urban areas.

Beneficiaries will also benefit in those cases in which suppliers previously did not accept assignment and billed the beneficiary the difference between the Medicare program allowed amount and their actual charge, because under the fee schedule all suppliers must accept assignment.

E. Conclusion

We anticipate that the ambulance fee schedule amounts for entities that have historically received lower than average payment rates will be relatively higher and the fee schedule amounts for entities that have historically received higher than average payment rates will be relatively lower. Generally, this will mean higher rates in the future for rural transports, lower rates in the future for urban transports, and higher rates in the future for air ambulance services. We believe that the statutory requirement to establish mechanisms to control increases in expenditures for ambulance services under Part B of the Medicare program is met by continuance of the application of the inflation factors prescribed in the statute.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects Affected in 42 CFR Part 410

Ambulances, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 410 – SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

A. Part 410 is amended as set forth below:

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B – Medical and Other Health Services

2. Section 410.40 is amended by:

A. Revising paragraph (b).

B. Revising paragraph (d)(1).

C. Revising paragraph (d)(2).

D. Revising the paragraph (d)(3) heading and introductory text.

E. Revising paragraph (d)(3)(i).

F. Adding new paragraphs (d)(3)(iii), (d)(3)(iv), and (d)(3)(v).

The revisions and additions read as follows:

§ 410.40 Coverage of ambulance services.

* * *

(b) *Levels of service.* Medicare covers the following levels of ambulance service, which are defined in § 414.605 of this chapter:

(1) Basic life support (BLS) (emergency and non-emergency).

(2) Advanced life support, level 1 (ALS1) (emergency and nonemergency).

(3) Advanced life support, level 2 (ALS2).

(4) Paramedic ALS intercept (PI).

(5) Specialty care transport (SCT).

(6) Fixed wing transport (FW).

(7) Rotary wing transport (RW).

* * *

(d) *Medical necessity requirements* –

(1) *General rule.* Medicare covers ambulance services, including fixed wing and rotary wing ambulance services, only if they are furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary. Nonemergency transportation by ambulance is appropriate if either: the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation. It is one factor that is considered in medical

necessity determinations. For a beneficiary to be considered bed-confined, the following criteria must be met:

(i) The beneficiary is unable to get up from bed without assistance.

(ii) The beneficiary is unable to ambulate.

(iii) The beneficiary is unable to sit in a chair or wheelchair.

(2) *Special rule for nonemergency, scheduled, repetitive ambulance services.* Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met. The physician's order must be dated no earlier than 60 days before the date the service is furnished.

(3) *Special rule for nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis.* Medicare covers medically necessary nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis under one of the following circumstances:

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a written order from the beneficiary's attending physician, within 48 hours after the transport, certifying that the medical necessity requirements of paragraph (d)(1) of this section are met.

* * *

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a signed certification statement must be obtained from either the physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), or discharge planner, who has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished. This individual must be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported. Medicare regulations for PAs, NPs, and CNSs apply and all applicable State licensure laws apply; or,

(iv) If the ambulance provider or supplier is unable to obtain the required certification within 21 calendar days following the date of the service, the ambulance supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (d)(3)(iii) of this section.]

(v) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the signed certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

* * *

PART 414 - PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

B. Part 414 is amended as set forth below:

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, 1395rr(b)(1)).

2. Section 414.1 is revised to read as follows:

§ 414.1 Basis and scope.

This part implements the following provisions of the Act:

1802 – Rules for private contracts by Medicare beneficiaries.

1833 – Rules for payment for most Part B services.

1834(a) and (h) – Amounts and frequency of payments for durable medical equipment and for prosthetic devices and orthotics and prosthetics.

1834(l) – Establishment of a fee schedule for ambulance services.

1834(m) – Rules for Medicare reimbursement for telehealth services.

1848 – Fee schedule for physician services.

1881(b) – Rules for payment for services to ESRD beneficiaries.

1887 – Payment of charges for physician services to patients in providers.

3. A new subpart H, consisting of §§ 414.601 through 414.625, is added to read as follows:

Subpart H – Fee Schedule for Ambulance Services

Sec.

414.601 Purpose.

414.605 Definitions.

414.610 Basis of payment.

414.615 Transition to the ambulance fee schedule.

414.620 Publication of the ambulance fee schedule.

414.625 Limitation on review.

Subpart H – Fee Schedule for Ambulance Services

§ 414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see § 413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule.

§ 414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively

referred to as "ground") ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

Advanced life support (ALS) intervention means a procedure that is, in accordance with State and local laws, beyond the scope of authority of an emergency medical technician-basic (EMT-Basic).

Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

Advanced life support, level 2 (ALS2) means either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures:

(1) Manual defibrillation/cardioversion.

(2) Endotracheal intubation.

(3) Central venous line.

(4) Cardiac pacing.

(5) Chest decompression.

(6) Surgical airway.

(7) Intraosseous line.

Advanced life support (ALS) personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. The EMT-Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT-Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a limited number of medications. The EMT-Paramedic is defined as possessing the qualifications of the EMT-Intermediate and also, in accordance with State and local laws, as having enhanced skills that include being able to administer additional interventions and medications.

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by an individual who is qualified in accordance with State and local laws as an emergency medical technician-basic (EMT-Basic). These laws may vary from State to State. For example, only in some States is an EMT-Basic permitted to operate limited equipment on board the vehicle, assist more qualified personnel in performing assessments and interventions, and establish a peripheral intravenous (IV) line.

Conversion factor (CF) is the dollar amount established by CMS that is multiplied by relative value units to produce ground ambulance service base rates.

Emergency response means responding immediately at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance supplier begins as quickly as possible to take the steps necessary to respond to the call.

Fixed wing air ambulance (FW) means transportation by a fixed wing aircraft that is certified as a fixed wing air ambulance and such services and supplies as may be medically necessary.

Geographic adjustment factor (GAF) means the practice expense (PE) portion of the geographic practice cost index (GPCI) from the physician fee schedule as applied to a percentage of the base rate. For ground ambulance services, the PE portion of the GPCI is applied to 70 percent of the base rate for each level of service. For air ambulance services, the PE portion of the GPCI is applied to 50 percent of the applicable base rate.

Goldsmith modification means the recognition of rural areas within certain Standard Metropolitan Statistical Areas wherein a census tract is deemed to be rural when located within a large metropolitan county of at least 1,225 square miles, but is so isolated from the metropolitan core of that county by distance or physical features as to be more rural than urban in character.

Loaded mileage means the number of miles the Medicare beneficiary is transported in the ambulance vehicle.

Paramedic ALS intercept (PI) means EMT-Paramedic services furnished by an entity that does not furnish the

ground ambulance transport, provided the services meet the requirements specified in § 410.40(c) of this chapter.

Point of pick-up means the location of the beneficiary at the time he or she is placed on board the ambulance.

Relative value units (RVUs) means a value assigned to a ground ambulance service.

Rotary wing air ambulance (RW) means transportation by a helicopter that is certified as an ambulance and such services and supplies as may be medically necessary.

Rural adjustment factor (RAF) means an adjustment applied to the base payment rate when the point of pick-up is located in a rural area.

Rural area means an area located outside a Metropolitan Statistical Area (MSA), or a New England County Metropolitan Area (NECMA), or an area within an MSA that is identified as rural by the Goldsmith modification.

Specialty care transport (SCT) means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

§ 414.610 Basis of payment.

(a) *Method of payment.* Medicare payment for ambulance services is based on the lesser of the actual charge or the applicable fee schedule amount. The fee

schedule payment for ambulance services equals a base rate for the level of service plus payment for mileage and applicable adjustment factors. Except for services furnished by certain critical access hospitals or entities owned and operated by them, as described in § 413.70(b) of this chapter, all ambulance services are paid under the fee schedule specified in this subpart (regardless of the vehicle furnishing the service).

(b) *Mandatory assignment.* Effective with implementation of the ambulance fee schedule described in § 414.601 (that is, for services furnished on or after April 1, 2002), all payments made for ambulance services are made only on an assignment-related basis. Ambulance suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts. Violations of this requirement may subject the provider or supplier to sanctions, as provided by law (part 402 of this chapter).

(c) *Formula for computation of payment amounts.* The fee schedule payment amount for ambulance services is computed according to the following provisions:

(1) *Ground ambulance service levels.* The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate. The service-level base rate is then adjusted by the GAF. Compare this amount to the actual charge. The lesser of the charge or the GAF adjusted base rate amount is added to the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is applied to the ground mileage

rate to determine the appropriate payment rates. The RVU scale for the ambulance fee schedule is as follows:

Service level	Relative value units (RVUs)
BLS	1.00
BLS-Emergency	1.60
ALS1	1.20
ALS1-Emergency	1.90
ALS2	2.75
SCT	3.25
PI	1.75

(2) *Air ambulance service levels.* The base payment rate for the applicable type of air ambulance service is adjusted by the GAF and, when applicable, by the appropriate RAF to determine the amount of payment. Air ambulance services have no CF or RVUs. This amount is compared to the actual charge. The lesser of the charge or the adjusted GAF rate amount is added to the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is also applied to the air mileage rate.

(3) *Loaded mileage.* Payment is made for each loaded mile. Air mileage is based on loaded miles flown as expressed in statute miles. There are three mileage payment rates: a rate for FW services, a rate for RW services, and a rate for all levels of ground transportation.

(4) *Geographic adjustment factor (GAF).* For ground ambulance services, the PE portion of the GPCI from the physician fee schedule is applied to 70 percent of the base rate for ground ambulance services. For air ambulance services, the PE portion of the physician fee schedule

GPCI is applied to 50 percent of the base rate for air ambulance services.

(5) *Rural adjustment factor (RAF).* For ground ambulance services where the point of pickup is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles and by 25 percent for miles 18 through 50. The standard mileage rate applies to every mile over 50 miles. For air ambulance services where the point of pickup is in a rural area, the total payment is increased by 50 percent; that is, the rural adjustment factor applies to the sum of the base rate and the mileage rate.

(6) *Multiple patients.* The allowable amount per beneficiary for a single ambulance transport when more than one patient is transported simultaneously is based on the total number of patients (both Medicare and non-Medicare) on board. If two patients are transported simultaneously, then the payment allowance for the beneficiary (or for each of them if both patients are beneficiaries) is equal to 75 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus 50 percent of the applicable mileage payment allowance. If three or more patients are transported simultaneously, the payment allowance for the beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus the applicable mileage payment allowance divided by the number of patients on board.

(d) *Payment.* Payment, in accordance with this subpart, represents payment in full (subject to applicable Medicare Part B deductible and coinsurance requirements as described in subpart G of part 409 of this chapter or in

subpart I of part 410 of this chapter) for all services, supplies, and other costs for an ambulance service furnished to a Medicare beneficiary. No direct payment will be made under this subpart if billing for the ambulance service is required to be consolidated with billing for another benefit for which payment may be made under this chapter.

(e) *Point of pick-up.* The zip code of the point of pick-up must be reported on each claim for ambulance services so that the correct GAF and RAF may be applied, as appropriate.

(f) *Updates.* The CF, the air ambulance base rates, and the mileage rates are updated annually by an inflation factor established by law. The inflation factor is based on the consumer price index for all urban consumers (CPI-U) (U.S. city average) for the 12-month period ending with June of the previous year.

(g) *Adjustments.* The Secretary will annually review rates and will adjust the CF and air ambulance rates if actual experience under the fee schedule is significantly different from the assumptions used to determine the initial CF and air ambulance rates. The CF and air ambulance rates will not be adjusted solely because of changes in the total number of ambulance transports.

§ 414.615 Transition to the ambulance fee schedule.

The fee schedule for ambulance services will be phased in over 5 years beginning April 1, 2002. Subject to the first sentence in § 414.610(a), payment for services furnished during the transition period is made based on a combination of the fee schedule payment for ambulance

services and the amount the program would have paid absent the fee schedule for ambulance services, as follows:

(a) *2002 Payment.* For services furnished in 2002, the payment for the service component, the mileage component and, if applicable, the supply component is based on 80 percent of the reasonable charge for independent suppliers or on 80 percent of reasonable cost for providers, plus 20 percent of the ambulance fee schedule amount for the service and mileage components. The reasonable charge or reasonable cost portion of payment in CY 2002 is equal to the supplier's reasonable charge allowance or provider's reasonable cost allowance for CY 2001, multiplied by the statutory inflation factor for ambulance services.

(b) *2003 Payment.* For services furnished in CY 2003, payment is based on 60 percent of the reasonable charge or reasonable cost, as applicable, plus 40 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2003 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2002, multiplied by the statutory inflation factor for ambulance services.

(c) *2004 Payment.* For services furnished in CY 2004, payment is based on 40 percent of the reasonable charge or reasonable cost, as applicable, plus 60 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2004 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2003, multiplied by the statutory inflation factor for ambulance services.

(d) *2005 Payment.* For services furnished in CY 2005, payment is based on 20 percent of the reasonable

charge or reasonable cost, as applicable, plus 80 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2005 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2004, multiplied by the statutory inflation factor for ambulance services.

(e) *2006 and Beyond Payment.* For services furnished in CY 2006 and thereafter, the payment is based solely on the ambulance fee schedule amount.

(f) *Updates.* The portion of the transition payment that is based on the existing payment methodology (that is, the non-fee-schedule portion) is updated annually for inflation by a factor equal to the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending with June of the previous year. The CY 2002 inflation update factor used to update the 2001 payment amounts is applied to the annualized (average) payment amounts for CY 2001. For the period January 1, 2001 through June 30, 2001, the inflation update factor is 2.7 percent. For the period July 1, 2001 through December 31, 2001, the inflation update factor is 4.7 percent. The average for the year is 3.7 percent. Thus, the annualized (average) CY 2001 payment amounts used to derive the CY 2002 payment amounts are equivalent to the CY 2001 payment amounts that would have been determined had the inflation update factor for the entire CY 2001 been 3.7 percent. Both portions of the transition payment (that is, the portion that is based on reasonable charge or reasonable cost and the portion that is based on the ambulance fee schedule) are updated annually for inflation by the inflation factor described in § 414.610(f).

(g) *Exception.* There will be no blended payment allowance as described in paragraphs (a), (b), (c), and (d) of this section for ground mileage in those States where the Medicare carrier paid separately for all out-of-county ground ambulance mileage, but did not, before the implementation of the Medicare ambulance fee schedule, make a separate payment for any ground ambulance mileage within the county in which the beneficiary was transported. Payment for ground ambulance mileage in that State will be made based on the full ambulance fee schedule amount for ground mileage. This exception applies only to carrier-processed claims and only in those States in which the carrier paid separately for out-of-county ambulance mileage, but did not make separate payment for any in-county mileage throughout the entire State.

§ 414.620 Publication of the ambulance fee schedule.

Changes in payment rates resulting from incorporation of the annual inflation factor described in § 414.610(f) will be announced by notice in the **Federal Register** without opportunity for prior comment. CMS will follow applicable rulemaking procedures in publishing revisions to the fee schedule for ambulance services that result from any factors other than the inflation factor.

§ 414.625 Limitation on review.

There will be no administrative or judicial review under section 1869 of the Act or otherwise of the amounts established under the fee schedule for ambulance services, including the following:

(a) Establishing mechanisms to control increases in expenditures for ambulance services.

(b) Establishing definitions for ambulance services that link payments to the type of services provided.

(c) Considering appropriate regional and operational differences.

(d) Considering adjustments to payment rates to account for inflation and other relevant factors.

(e) Phasing in the application of the payment rates under the fee schedule in an efficient and fair manner.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare – Supplementary Medical Insurance Program)

Dated: December 7, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 19, 2001.

Tommy G. Thompson,

Secretary.

68 FR 18654-02

NOTICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1256-N]

RIN 0938-AM60

Medicare Program; Notice of Ambulance Fee Schedule in Accordance With Federal District Court Order

Wednesday, April 16, 2003

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the steps CMS is taking to comply with the Order in Lifestar Ambulance Service, Inc. v. United States, No. 4:02-CV-127-1 (M.D. Ga. Jan. 16, 2003) Medicare Covered Ambulance Services.

EFFECTIVE DATE: This notice is effective on April 16, 2003.

FOR FURTHER INFORMATION CONTACT: Anne Tayloe, (410) 786-4546.

SUPPLEMENTARY INFORMATION:

I. Background

Section 4531 of the Balanced Budget Act of 1997 (BBA) required the Secretary of the Department of Health and Human Services to establish a national fee schedule (FS) for payment of ambulance services through a negotiated rulemaking process. The statute provided that the Secretary phase in the application of payment rates under

the FS in an efficient and fair manner and that the aggregate amount of payment for such services under the new FS not exceed the amount that would have been paid under the old system (42 U.S.C. § 1395m(l) (1), (2), (3)). The BBA provided that the FS would apply to services furnished on or after January 1, 2000.

The September 12, 2000 proposed rule (65 FR 55078) and the February 27, 2002 final rule (67 FR 9100) both provide for payment for ambulance services to be made in two parts: a base rate and a payment for mileage. Section 423 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which was passed after the publication of the proposed rule and prior to the promulgation of the final rule, provided that during the phase-in of the FS there would be full payment of any national mileage rate for ambulance services furnished by suppliers in States where the Medicare carrier did not previously pay separately for all mileage within the county from which the beneficiary is transported. Two States have been identified as qualifying under this provision: North Carolina and Tennessee. The BIPA states that this provision shall apply to services furnished on or after July 1, 2001. The FS was implemented on April 1, 2002 by the February 27, 2002 final rule. The final rule announced the 5-year phase-in that is based on a blend of a percentage of the payment based on the old payment system with a percentage of the payment based on the FS according to the following schedule:

Calendar year	Percentage of old payment system	Percentage of fee schedule
2002*	80	20
2003	60	40
2004	40	60
2005	20	80
2006	0	100

FN* April 1, 2002 through December 31, 2002 only.

The full national FS mileage rate in those States that qualify for section 423 of the BIPA (North Carolina and Tennessee) has been paid as of April 1, 2002.

In Lifestar Ambulance Service, Inc. v. United States, No. 4:02-CV-127-1 (M.D. Ga. Jan 16, 2003), three ambulance suppliers seeking to represent a nationwide class of ambulance suppliers sued the Secretary, arguing that he has no discretion to give the FS an effective date other than January 1, 2000. The district court agreed with the plaintiff suppliers and issued an order certifying a nationwide class of ambulance suppliers and requiring the Secretary to adopt a FS for the January 1, 2000 through March 31, 2002 period. The court's decision also requires the Secretary to pay full mileage in accordance with the BIPA provision for the July 1, 2001 through March 31, 2002 period. Id. at 20-21.

II. Provisions of the Notice

The purpose of this notice is to comply with the court's order requiring a FS to be established for the January 1, 2000 through March 31, 2002 period. By this notice, the Secretary is establishing a FS based on the FS

as described in the February 27, 2002 final rule, with a modified phase-in as follows:

Calendar year	Percentage of old payment system	Percentage of fee schedule
2000*	95	5
2001	90	10
2002	80	20

FN* January 1, 2002 through March 31, 2002.

Additionally, in accordance with the district court's order, the Medicare program will pay full BIPA mileage for services provided on or after July 1, 2001.

The BBA provided that the Secretary shall phase in the application of payment rates under the FS in an efficient and fair manner. As previously detailed, based on the discretion afforded the Secretary by the BBA, the final rule published on February 27, 2002 provided for a linear progression from the prior payment system to FS payments, commencing with a 20 percent/80 percent blended payment for the last three quarters of FY 2002, and ending with a 100 percent FS payment for FY 2006.

Five percent, 10 percent, and 20 percent is the most appropriate progression of blending percentages for the January 1, 2000 through March 31, 2002 period. For the first quarter of 2002, 20 percent is the same blending percentage as the percentage already used for the FS during the other 9 months in 2002. The 5 percent and 10 percent are the most appropriate percentages for 2000 and 2001, in that they comply with the statutory requirement for an efficient and fair phase-in, and are consistent with the linear progression in blending percentages promulgated in the February 27, 2002 final rule.

The Lifestar court recognized the Secretary's statutory discretion to set the phase-in percentages for the January 1, 2000 through March 31, 2002 period. The court also stated that these phase-in percentages must provide meaningful relief to the Lifestar plaintiffs. The FS described in this notice provides meaningful relief as evidenced in more detail under the impact section, below. We estimate that 2/3 of 15,000 suppliers will be receiving a total of $81 million for this period.

The statute at 42 U.S.C. 1395 (m) (l) (3) (B) provides that FS payment amounts in subsequent years to the first year of the FS be set equal to the FS payment amounts from the previous year increased by a statutorily prescribed inflation factor. The FS final rule used data from 1998 and inflated it using the statutorily prescribed inflation factors to obtain the 2002 amounts. See 67 FR 9100, 9125. To determine the FS amounts for earlier years (that is, the period of January 1, 2000 through December 31, 2001), we have deflated the FS amounts for 2002 by the same statutorily prescribed ambulance inflation factors. These deflation factors are:

Calendar year	Deflation Percentage
2000/2001	3.7
2001/2002	2.2

III. Appeal of Lifestar Decision/Recoupment

The Secretary has appealed the Lifestar decision. In the event the district court's decision is reversed on appeal, any FS or BIPA mileage payment made in accordance with this notice for the January 1, 2000 through March 31, 2002 period will be subject to recoupment.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

The court's January 16, 2003 order in Lifestar requires establishment of a FS for the January 1, 2000 through March 31, 2002 period within 90-days of the date of the order. It would be impracticable to provide a period for prior notice and comment and still meet the 90-day deadline. In fact, the Congress has recognized the impracticability of providing prior notice and comment where a statutory provision must be implemented within 150 days. See 42 U.S.C. 1395hh (b) (2) (B) (providing that a notice of proposed rulemaking is not required if a statute establishes a specific deadline for implementation that is less than 150 days from enactment).

Therefore, we find good cause to waive the notice of proposed rulemaking and comment period with respect to the issuance of this notice.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget

under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102 (b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

There are approximately 15,000 suppliers nationwide that submit claims to Medicare for ambulance services. The Medicare program pays approximately $2.1 billion in Medicare benefits per year for these services. We estimate that approximately two-thirds of suppliers will benefit from this January 1, 2000 through March 31, 2002 FS and that the aggregate amount of program spending will be approximately $81 million. The break out of this expenditure is as follows:

Calendar year	Program expenditures (in millions)
2000	$16
2001	$43
2002	$22
Total	$81

These amounts include approximately $16 million by which suppliers in North Carolina and Tennessee will benefit due to implementation of the BIPA ambulance mileage provision for the period of July 1, 2001 through March 31, 2002.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The aggregate amount of program spending to comply with the court's order will be approximately $81 million. Therefore this notice is not a major notice as defined in Title 5, United States Code, section 804(2) and is not an economically significant notice under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not considered to be small entities. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100

beds. We have determined that this notice will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice has no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial effect on State or local governments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare – Supplementary Medical Insurance Program)

Dated: April 1, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 11, 2003.

Tommy G. Thompson,

Secretary.

(2)

No. 04-430

In the Supreme Court of the United States

LIFESTAR AMBULANCE SERVICE, INC., ET AL.,
PETITIONERS

v.

UNITED STATES OF AMERICA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the district court could properly exercise mandamus jurisdiction under 28 U.S.C. 1361 over petitioners' challenge to Medicare regulations governing the reimbursement of ambulance services.

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In the Supreme Court of the United States

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LIFESTAR AMBULANCE SERVICE, INC., ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-11a) is reported at 365 F.3d 1293. The opinion of the district court (Pet. App. 12a-43a) is reported at 211 F.R.D. 688.

JURISDICTION

The judgment of the court of appeals was entered on April 16, 2004. A petition for rehearing was denied on June 29, 2004 (Pet. App. 44a-45a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Petitioners challenge regulations implementing a fee schedule governing the reimbursement of ambulance

services under Medicare. The court of appeals held that petitioners must raise their challenge under the specific review procedures of the Medicare Act, 42 U.S.C. 1395 *et seq.*, and could not circumvent those procedures by resorting to the general mandamus statute under 28 U.S.C. 1361.

1. The Medicare program, established in 1965 by Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*, is a federally subsidized health insurance program for the elderly and certain disabled people. 42 U.S.C. 1395c, 1395d. Part A of the program provides insurance for covered inpatient hospital and related post-hospital services. 42 U.S.C. 1395x(m). Part B is a voluntary supplementary insurance program covering physicians' services and certain other medical and health services. 42 U.S.C. 1395k, 1395*l*, 1395x(s).

The Medicare statute provides that ambulance services are covered under Part B "where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations." 42 U.S.C. 1395x(s)(7). Medicare accordingly covers ambulance services, in both emergency and non-emergency situations, if the use of an ambulance is necessary in light of the beneficiary's medical condition at the time of transport, and if the ambulance service meets certain vehicle and crew requirements. 42 C.F.R. 410.40-410.41.

Medicare previously paid for ambulance services on a "reasonable cost" basis, if services were furnished by a hospital-based provider, or a "reasonable charge" basis, if services were furnished by a free-standing ambulance service supplier. 67 Fed. Reg. 9102 (2002). Those retrospective methodologies based payments on the costs or charges actually incurred. In the Balanced Budget Act of 1997, Congress directed the Secretary of

Health and Human Services (HHS) to establish a national fee schedule setting forth pre-determined amounts that Medicare would pay for ambulance services. Pub. L. No. 105-33, § 4531(b), 111 Stat. 451 (42 U.S.C. 1395m(*l*)).

The Balanced Budget Act of 1997 provides that in developing a fee schedule, the Secretary shall establish mechanisms to control increases in expenditures, establish definitions for ambulance services that link payments to the type of services furnished, consider appropriate regional and operational differences, and consider adjustments for inflation and other "relevant factors." 42 U.S.C. 1395m(*l*)(2)(A)-(D). The Act directs the Secretary to "phase in the application of the payment rates under the fee schedule in an efficient and fair manner." 42 U.S.C. 1395m(*l*)(2)(E). It mandates that the fee schedule be "budget neutral" by requiring that payments under the schedule in the year 2000 not exceed the inflation-adjusted expenditures that would have been made under prior law. 42 U.S.C. 1395m(*l*)(3). And it provides that "[t]he amendments made by this subsection shall apply to services furnished on or after January 1, 2000." Pub. L. No. 105-33, § 4531(b)(3), 111 Stat. 452 (42 U.S.C. 1395m(*l*) note).

On September 12, 2000, the Secretary promulgated a proposed ambulance fee schedule rule that, *inter alia*, included payments based on mileage covered by the ambulance. 65 Fed. Reg. 55,078. The rule proposed that the schedule take effect on January 1, 2001, and that the fee schedule be phased in over a four-year transition period during which some percentage of the payment would be based on the prior, cost or charge-based methodology, and an increasing percentage of the payment would be based on the new fee schedule. *Id.* at 55,085. The Secretary observed that the proposed

effective date for implementing the fee schedule did not meet the statutory deadline set out in the Balanced Budget Act of 1997. The Secretary explained, however, that the development of the fee schedule had been delayed by the burdens of ensuring that HHS's massive computer systems would be "Y2K" compliant and not disrupted by difficulties in accurately recognizing the calendar year 2000, and by obligations to implement other Medicare changes mandated by the Balanced Budget Act. *Id.* at 55,079.

On December 21, 2000, before the proposed rule was finalized, Congress enacted legislation amending one component of the proposed fee schedule: the mileage payment to be made to certain ambulance service suppliers. The statute amended the phase-in provisions of the existing ambulance fee schedule statute to provide that the

> phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554 (App. F —H.R. 5661), § 423(b), 114 Stat. 2763A-518. Congress specified that the amendment "shall apply to services furnished on or after July 1, 2001." § 423(b)(2), 114 Stat. 2763A-518.

On February 27, 2002, the Secretary promulgated the final fee schedule rule. 67 Fed. Reg. 9100. The final rule enlarged the transition period for phasing in the

new fee schedule to five years to accommodate ambulance provider requests for a longer adjustment period. *Id.* at 9118-9119. In addition, the final rule postponed the effective date until April 1, 2002. *Id.* at 9100. The Secretary explained that

> [i]n the September 12, 2000 proposed rule, we indicated our intention to implement the fee schedule beginning January 1, 2001. However, although the proposed rule was largely based on an agreement reached as part of the negotiated rulemaking process with representatives of the ambulance industry and other interests, we received over 340 public comments. We did not have sufficient time to carefully consider all comments and publish a final rule in time to implement the fee schedule by January 1, 2001.

Id. at 9104.

2. Petitioners are a class of ambulance service operators. They allege that the aforementioned Acts require the new fee schedule to be applied to services provided from January 1, 2000, forward, and that the Secretary therefore erred in establishing a later effective date. The district court found that it had mandamus jurisdiction under 28 U.S.C. 1361 over petitioners' claims and ordered the Secretary to adopt a fee schedule applicable to services rendered on or after the earlier effective dates specified by statute. Pet. App. 32a.

The district court held that the Medicare Act does not preclude mandamus jurisdiction, and that petitioners satisfied the criteria for invoking mandamus jurisdiction. Pet. App. 18a-19a, 20a-26a. The court reasoned that the Secretary had a nondiscretionary duty to establish the fee schedule and mileage provi-

sions by the statutorily-specified dates. *Id.* at 20a-22a. The court further reasoned that petitioners had no alternative means of securing review because the administrative review procedures established by Medicare were futile. *Id.* at 23a-26a. On the merits, the court granted summary judgment for petitioners. *Id.* at 20a-30a.

3. The court of appeals reversed, holding that the district court had erred in exercising subject matter jurisdiction under the mandamus statute. The court found it unnecessary to decide whether the Medicare Act forecloses mandamus jurisdiction, expressly stating that "[w]e assume, without deciding, that mandamus jurisdiction is not barred by 42 U.S.C. § 405(h) and, therefore, is available for a claim arising under the Medicare statute." Pet. App. 4a n.3. It held, however, that, even assuming mandamus jurisdiction is available, "[p]laintiffs cannot invoke the extraordinary remedy of mandamus because they have an 'alternative avenue of relief.'" *Id.* at 4a (quoting *Mallard* v. *United States Dist. Ct.*, 490 U.S. 296, 309 (1989)). The court explained that "[t]he Medicare Act establishes a comprehensive remedial scheme, providing both administrative hearing rights for aggrieved providers, such as [petitioners], and judicial review of the Secretary's final decisions." *Id.* at 4a-5a. The court further observed that "[i]t is undisputed that [petitioners] did not resort to these administrative remedies." *Id.* at 5a. The court of appeals accordingly vacated the district court's judgment and remanded with instructions to dismiss for want of subject matter jurisdiction. *Id.* at 11a.

ARGUMENT

The court of appeals' decision is correct and consistent with this Court's precedents holding that man-

damus is an extraordinary remedy that is not available if the plaintiff has an adequate, alternative means of judicial review.

1. The Medicare Act generally makes federal jurisdiction over all claims arising under the Medicare Act contingent on presentment of a claim to the Secretary and exhaustion of statutorily-prescribed administrative remedies. With respect to ambulance services and other items paid under Part B, the Act, as in effect at the time the complaint was filed,* and subject to amount-in-controversy limitations not relevant here, provides that individuals and health care providers who are aggrieved by a reimbursement determination have a right to a hearing on their claim before the Secretary under 42 U.S.C. 405(b), and to judicial review of the Secretary's final decision under 42 U.S.C. 405(g). 42 U.S.C. 1395ff(b)(1)(A).

The Act provides that a party may obtain judicial review "after any final decision of the [Secretary] made after a hearing to which [the provider] was a party" by filing a civil action in district court within 60 days after notice of the decision. 42 U.S.C. 405(g). Finally, 42 U.S.C. 405(h), which is incorporated by reference into the Medicare Act, 42 U.S.C. 1395ii, makes the Act the

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* Congress amended 42 U.S.C. 1395ff to impose processing deadlines on certain administrative appeals and to require a claimant to exhaust an additional level of administrative reconsideration before seeking judicial review. Pub. L. No. 106-554 (App. F— H.R. 5661), § 1(a)(6), 114 Stat. 2763; § 521, 114 Stat. 2763A-534. The amendments, however, do not apply to initial administrative determinations made before October 1, 2002, and do not otherwise alter the Act's requirements that condition judicial review on presentment of a claim to the Secretary and exhaustion of administrative remedies.

exclusive means of obtaining review of the Secretary's final decision. Section 405(h) provides:

> The findings and decisions of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28, [United States Code], to recover on any claim arising under this [title].

42 U.S.C. 405(h).

In short, the above provisions condition federal jurisdiction over Medicare claims on presentment of the claim to the Secretary and exhaustion of administrative remedies. They do so by establishing administrative hearing rights, by providing that final decisions made after a hearing are judicially reviewable *solely* under provisions of the Medicare statute, and by expressly foreclosing resort to the federal question jurisdiction provision of 28 U.S.C. 1331. *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 7-14 (2000); *Heckler* v. *Ringer*, 466 U.S. 602, 614-619 (1984); *Weinberger* v. *Salfi*, 422 U.S. 749, 760-761 (1975).

This Court has not resolved whether Section 405(h) bars resort to mandamus jurisdiction pursuant to 28 U.S.C. 1361. *Your Home Visiting Nurse Servs., Inc.* v. *Shalala*, 525 U.S. 449, 457 n.3 (1999) (declining to address the Secretary's contention that the second sentence of Section 405(h) bars mandamus jurisdiction); *Ringer*, 466 U.S. at 616. Some courts have concluded, however, that, with respect to essentially procedural claims arising under Medicare or other pertinent titles

of the Social Security Act, Section 405(h) does not foreclose mandamus jurisdiction where the standards for mandamus relief are otherwise satisfied. See, *e.g.*, *Ellis* v. *Blum*, 643 F.2d 68, 82 (2d Cir. 1981) (Section 405(h) "does not preclude assertion of § 1361 jurisdiction over claims essentially procedural in nature."); *Belles* v. *Schweiker*, 720 F.2d 509, 512 (8th Cir. 1983) ("[I]n cases like the present one, which involve claims essentially procedural in nature, § 405(h) presents no obstacle to mandamus jurisdiction."); *Burnett* v. *Bowen*, 830 F.2d 731, 738 (7th Cir. 1987) ("Congress intended to preserve mandamus jurisdiction for claims that are procedural in nature."); *Monmouth Med. Ctr.* v. *Thompson*, 257 F.3d 807 (D.C. Cir. 2001) (mandamus jurisdiction available to compel Secretary to comply with regulations governing reopening of final reimbursement determination).

Petitioners argue that the court of appeals' decision, in denying mandamus relief in this particular case, conflicts with the above appellate authority. Pet. 14-15. Petitioners reason that the court of appeals' decision, by recognizing the availability of alternative remedies established by the Medicare Act, effectively renders mandamus jurisdiction unavailable in all instances. Pet. 22-25. That is not correct. The decision below "assume[d], without deciding, that mandamus jurisdiction is *not* barred by 42 U.S.C. § 405(h) and, therefore *is* available for a claim arising under the Medicare statute." Pet. App. 4a n.3 (emphasis added). The court of appeals' decision thus expressly did not decide whether mandamus jurisdiction is available for claims arising under Medicare.

The court of appeals correctly found such consideration unnecessary because petitioners' undisputed failure to follow the administrative and judicial review

procedures specified in the Act, 42 U.S.C. 405(b) and (g), precluded their ability to meet the traditional standards for mandamus relief, thereby obviating the need to address whether mandamus relief might be appropriate in other circumstances. Pet. App. 4a-5a. That holding is fully consistent with this Court's similar refusal to decide whether mandamus relief would ever be available for Medicare and Social Security claims because the plaintiff otherwise could not meet the standards for mandamus relief, *i.e.*, a clear non-discretionary duty and unavailability of alternative avenues of relief. *Heckler*, 466 U.S. at 616 ("We have on numerous occasions declined to decide whether the third sentence of § 405(h) bars mandamus jurisdiction * * * because we have determined that jurisdiction was otherwise available under § 405(g)."); accord *Your Home Visiting Nurse Servs.*, 525 U.S. at 457 & n.3 (plaintiff failed to show existence of a clear nondiscretionary duty).

Nothing in the court of appeals' decision suggests or purports to hold that Medicare's administrative remedies will be adequate in each and every instance, without regard to the nature and circumstances of the claim. It thus does not, as petitioners maintain, foreclose mandamus jurisdiction in an appropriate case. For instance, the court of appeals did not confront a circumstance where the Act itself provides no administrative or judicial review of a final decision of the Secretary. Cf. *Your Home Visiting Nurse Servs.*, 525 U.S. at 453-454 (holding an intermediary's refusal to reopen a reimbursement decision is not subject to review under the Act).

2. The court of appeals decision is also consistent with the standards for mandamus relief set forth in this Court's precedents. The mandamus jurisdiction con-

ferred by 28 U.S.C. 1361 "is intended to provide a remedy for a plaintiff only if he has exhausted all other avenues of relief and only if the defendant owes him a clear nondiscretionary duty." *Ringer*, 466 U.S. 602, 616 (1984). It is a narrow remedy reserved for extraordinary circumstances and, as such, ordinarily "may not be resorted to as a mode of review where a statutory method of appeal has been prescribed." *Roche* v. *Evaporated Milk Ass'n*, 319 U.S. 21, 27-28 (1943).

The court of appeals correctly applied those standards in holding that mandamus jurisdiction could not be asserted over petitioners' claims. The court noted that Medicare's remedial scheme provides for administrative review followed by plenary judicial review of all claims arising under the Medicare statue, and concluded that, "[i]n the face of this comprehensive statutory scheme, it cannot be said that the second requirement for mandamus review—that there be no alternative avenues of relief—is met." Pet. App. 10a.

Petitioners argue that the remedy available under Medicare's jurisdictional scheme is not adequate. Petitioners thus assert that because they "can only obtain the relief they seek through an order directing a federal official to comply with the law, no 'other remedy' besides mandamus can possibly exist." Pet. 25-26. That contention lacks merit. Medicare's judicial review provisions afford the reviewing court plenary power to direct a federal official to comply with the law, and the court is fully empowered to enter any other injunctive or declaratory relief that the court deems appropriate. Cf. *Illinois Council*, 529 U.S. at 23 ("[A] court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide."). Petitioners thus err in asserting that the

assumption of mandamus jurisdiction pursuant to 28 U.S.C. 1361 affords the only avenue of relief on their claims. Medicare's jurisdictional scheme provides a fully adequate remedy, and the court of appeals therefore correctly held that mandamus relief was inappropriate in this case.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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In The Supreme Court of the United States

LIFESTAR AMBULANCE SERVICE, INC., *et al.*,

Petitioners,

v.

UNITED STATES OF AMERICA, *et al.*,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

Petitioners do not "challenge regulations implementing a fee schedule." (Br. for the Federal Respondents in Opp., at 1). Respondents serve up this idea in the very first sentence of their Statement of the Case to suggest this case is a garden variety administrative squabble to be considered and resolved administratively. But the "channeling" requirement which Respondents claim requires this case to go through the administrative process comes from a statute that by its very terms does not limit mandamus jurisdiction. Pet. App. 48a (42 U.S.C. § 405(g), (h)). By grafting a channeling requirement on all cases arising under the Medicare Act where a plaintiff seeks mandamus, the Eleventh Circuit opinion runs contrary to every circuit that has considered the issue. Mandamus jurisdiction is perfect and necessary for Petitioners' challenge to Respondents' failure to comply with the law, even where that law is part of the Medicare Act.

Congress directed that Respondents establish a fee schedule for the payment of ambulance suppliers who furnished services to Medicare beneficiaries. Congress further mandated that this fee schedule "shall apply to services furnished on or after January 1, 2000." Pet. App. 58a (Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4531(b)(3) ("BBA")). In the Benefits Improvement and Protection Act of 2000 ("BIPA"), Congress directed that in addition to the changes mandated by the BBA, these suppliers should also receive "full payment of any national mileage rate" under the fee schedule for in-county miles. Pet. App. 63a (BIPA, Publ. L. No. 106-554, § 423(b)(1) (codified at 42 U.S.C. § 1395m(1)(2)(E))). Congress specifically directed that this amendment "shall apply to services furnished on or after July 1, 2001." Pet.

App. 63a (*Id.* at § 423(b)(2)). Respondents adopted regulations establishing a fee schedule that applies to services furnished on or after April 1, 2002.

No fee schedule exists for the relevant time frame. Petitioners challenge Respondents' failure to adopt a regulation that complies with the clear Congressional directive. That is an omission. To remedy this failure to act, Respondents must be ordered to comply with the law. Mandamus jurisdiction provides an Article III court with the power to order a federal official to comply with the law. Pet. App. 46a (28 U.S.C. § 1361). In fact, mandamus is the *only* remedy available to force compliance with the law. When the district court ordered Respondents to adopt a fee schedule that complied with the BBA, it did not disturb the existing regulations applying to services furnished after April 1, 2002. An awareness that this case is not simply a challenge to existing regulations helps to highlight the important jurisdictional issue at hand.

Petitioners do not simply argue that the administrative process would be ineffectual and unable to force Respondents to comply with the law. That is not the point. No entity, not even an Article III court has the power to grant the specific relief Petitioners request except through mandamus. *See Nat'l Wildlife Fed'n v. United States,* 626 F.2d 917, 918 n.1 (D.C. Cir. 1980) ("An action purportedly requesting a mandatory injunction against a federal official is properly analyzed as one requesting mandamus.").

CONCLUSION

Petitioners respectfully ask that this case be set for argument so that the Court may address the significant jurisdictional issue regarding the relationship between 42 U.S.C. § 405(h) and 28 U.S.C. § 1361 and thereby resolve the conflict between the Eleventh Circuit and the other nine circuits that have addressed this issue by holding that § 405(h) does not bar consideration of whether mandamus jurisdiction exists.

Respectfully submitted,

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